

# Federal Register

Friday  
April 26, 1985

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## Selected Subjects

- Administrative Practice and Procedure**  
Occupational Safety and Health Review Commission
- Air Pollution Control**  
Environmental Protection Agency
- Aviation Safety**  
Federal Aviation Administration
- Chemicals**  
Environmental Protection Agency
- Credit Unions**  
National Credit Union Administration
- Crime Insurance**  
Federal Emergency Management Agency
- Crop Insurance**  
Federal Crop Insurance Corporation
- Endangered and Threatened Species**  
Fish and Wildlife Service
- Environmental Impact Statements**  
Food and Drug Administration
- Exports**  
International Trade Administration
- Flood Insurance**  
Federal Emergency Management Agency
- Government Contracts**  
Immigration and Naturalization Service

CONTINUED INSIDE





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## Selected Subjects

### Grant Programs—Education

Education Department

### Imports

Animal and Plant Health Inspection Service

### Loan Programs—Agriculture

Commodity Credit Corporation

### Loan Programs—Business

Farmers Home Administration

### Manpower Training Programs

Employment and Training Administration

### Marketing Agreements

Agricultural Marketing Service

### Milk Marketing Order

Agricultural Marketing Service

### Nuclear Power Plants and Reactors

Nuclear Regulatory Commission

### Radio

Federal Communications Commission

### Rent Subsidies

Housing and Urban Development Department

### Reporting and Recordkeeping Requirements

Food and Drug Administration

### Savings and Loan Associations

Federal Home Loan Bank Board

### Surface Mining

Surface Mining Reclamation and Enforcement Office

### Traffic Regulations

Federal Highway Administration



# Contents

Federal Register

Vol. 50, No. 81

Friday, April 26, 1985

- The President**  
**PROCLAMATIONS**  
 16449 Defense Transportation Day, National, and National Transportation Week (Proc. 5326)
- Executive Agencies**
- Agricultural Marketing Service**  
**RULES**  
 16451 Almonds grown in California  
 16451 Lemons grown in California and Arizona  
 Milk marketing orders:  
 16452 Middle Atlantic
- Agriculture Department**  
*See also* Agricultural Marketing Service; Animal and Plant Health Inspection Service; Commodity Credit Corporation; Farmers Home Administration; Federal Crop Insurance Corporation.  
**NOTICES**  
 Grants; availability, etc.:  
 16524 Competitive research grants program
- Air Force Department**  
**NOTICES**  
 Meetings:  
 16532 Scientific Advisory Board
- Animal and Plant Health Inspection Service**  
**RULES**  
 16457 Animal welfare standards; marine mammals; CFR correction  
 Exportation and importation of animals and animal products:  
 16458 Semen of ruminants or swine from countries where rinderpest or foot-and-mouth disease exists; interim rule affirmed
- Arts and Humanities, National Foundation**  
**NOTICES**  
 16580 Meetings; Sunshine Act
- Blind and Other Severely Handicapped, Committee for Purchase from**  
**NOTICES**  
 16530, 16531 Procurement list 1985; additions and deletions (2 documents)
- Centers for Disease Control**  
**NOTICES**  
 Grants and cooperative agreements:  
 16556 Acquired Immunodeficiency Syndrome (AIDS); transmission of human T-lymphotropic virus type III (HTLV-III) from infected mothers to their infants
- Civil Rights Commission**  
**NOTICES**  
 Meetings; State advisory committees:  
 16528 Georgia; date change  
 16528 Hawaii  
 16528 Idaho
- 16528 Maryland  
 16528 Ohio; cancellation  
 16528 Texas; time change  
 16529 Virginia
- Commerce Department**  
*See* International Trade Administration; Patent and Trademark Office.
- Commodity Credit Corporation**  
**RULES**  
 Loan and purchase programs:  
 16453 Cotton; warehouse approval standards  
**PROPOSED RULES**  
 Loan and purchase programs:  
 16504 Grain, etc.; warehouse approval standards  
**NOTICES**  
 16526 Contract fees, annual; grain and rice storage agreement, uniform; inquiry
- Customs Service**  
**NOTICES**  
 Tariff-rate quotas:  
 16577 Tuna fish
- Defense Department**  
*See* Air Force Department; Navy Department.
- Economic Regulatory Administration**  
**NOTICES**  
 Powerplant and industrial fuel use; prohibition orders, exemption requests, etc.:  
 16538 Applied Energy Sciences, Inc.
- Education Department**  
**RULES**  
 Special education and rehabilitative services:  
 16672 National Institute of Handicapped Research; innovation grants program, etc.  
**NOTICES**  
 Grants; availability, etc.:  
 16533 Magnet schools assistance program
- Employment and Training Administration**  
**RULES**  
 Job Training Partnership Act programs:  
 16473 Youth training; single unit charge agreements  
**NOTICES**  
 Adjustment assistance:  
 16568 AMEDCO Casket Hardware et al.  
 16568 ASARCO, Inc.  
 16568 AT&T Consumer Products et al.
- Employment Standards Administration**  
**NOTICES**  
 16606 Minimum wages for Federal and federally-assisted construction; general wage determination decisions, modifications, and supersedeas decisions (CA, CO, FL, HI, IL, IA, NV, NY, OH, OK, TX, and WI)



**Energy Department**

See also Economic Regulatory Administration;  
Federal Energy Regulatory Commission; Western  
Area Power Administration.

**NOTICES**

- Environmental statements; availability, etc.:  
16534 Aiken, SC  
Grants; availability, etc.:  
16535 Monitored retrievable storage facility  
Nuclear Waste Policy Act:  
16536 Monitored retrievable storage facility; candidate  
sites identification for a proposal to Congress,  
etc.

**Environmental Protection Agency****RULES**

- Air quality implementation plans; approval and  
promulgation; various States:  
16475 Montana  
Air quality planning purposes; designation of areas;  
16476 Montana  
Toxic substances:  
16477 Premanufacture notification exemptions;  
chemical substances manufactured in quantities  
of 1,000 kg or less per year

**PROPOSED RULES**

- Toxic substances:  
16519 4,4'-Methylenebis(2-chlorobenzeneamine);  
significant new uses

**NOTICES**

- Environmental statements; availability, etc.:  
16544 Agency statements; comment availability  
16545 Agency statements; weekly receipts  
16546 West Rehoboth Sanitary Sewer District, Sussex  
County, DE  
Meetings:  
16544 Science Advisory Board  
Pesticide, food, and feed additive petitions:  
16543 Union Carbide Agricultural Products Co. Inc., et  
al.  
Toxic and hazardous substances control:  
16540 Premanufacture exemption applications  
16539 Premanufacture exemption approvals  
16541, Premanufacture notices receipts (2 documents)  
16543  
16544 Review period termination  
Water pollution; discharge of pollutants (NPDES):  
16546 Michigan

**Equal Employment Opportunity Commission****NOTICES**

- 16579 Meetings; Sunshine Act

**Farmers Home Administration****RULES**

- Loan and grant programs:  
16455 Business and industrial loans

**Federal Aviation Administration****RULES**

- Airworthiness directives:  
16465 Boeing  
16466 Teledyne Continental  
16465 Teledyne Continental; correction  
16466 Jet routes  
16467 Standard instrument approach procedures  
16466 VOR Federal airways; correction (2 documents)

**PROPOSED RULES**

Airworthiness directives:

- 16511 Fairchild  
16514 Rolls-Royce, Ltd.

**Federal Communications Commission****RULES**

- Radio services, special:  
16500 Maritime services; portable ship station licenses  
and frequency assignments on Great Lakes;  
eligibility

**Federal Crop Insurance Corporation****PROPOSED RULES**

- Administrative regulations:  
16502 Reinsurance agreements

**Federal Emergency Management Agency****RULES**

- Federal crime insurance program:  
16494 Commercial crime insurance; rating plan, rate  
and premium changes, etc.  
Flood insurance; communities eligible for sale:  
16492 New York et al.

**Federal Energy Regulatory Commission****NOTICES**

- 16579 Meetings; Sunshine Act

**Federal Highway Administration****PROPOSED RULES**

- Engineering and traffic operations:  
16515 Uniform Traffic Control Devices Manual;  
amendments; advance notice

**NOTICES**

- Environmental statements; notice of intent:  
16577 LaPorte County et al., IN

**Federal Home Loan Bank Board****RULES**

- Federal Savings and Loan Insurance Corporation:  
16459 Over-the-counter financial options trading;  
accounting for financial options; final rule and  
request for comments

**Federal Maritime Commission****NOTICES**

- 16579 Meetings; Sunshine Act

**Federal Reserve System****NOTICES**

- 16579 Meetings; Sunshine Act

**Fish and Wildlife Service****RULES**

- Endangered and threatened species:  
16680 Rhizome fleabane

**Food and Drug Administration****RULES**

- Biological products:  
16474 Anti-human globulin; additional standards;  
reporting and recordkeeping requirements  
16636 National Environmental Policy Act; implementation  
NOTICES  
Food additive petitions:  
16558 Miles Laboratories, Inc.



- Food for human consumption:  
Identity standard deviation; market testing permits—  
16558 Bread, enriched  
16557 Collards, canned, mustard greens, etc.
- Health and Human Services Department**  
*See also* Centers for Disease Control; Food and Drug Administration; National Institutes of Health.
- NOTICES**  
16564 Agency information collection activities under OMB review
- Historic Preservation, Advisory Council**  
**NOTICES**  
16524 Programmatic memorandums of agreement: Fort Leavenworth, KS
- Housing and Urban Development Department**  
**RULES**  
Low income housing:  
16612 Housing assistance payments (Section 8); fair market rents for new construction and substantial rehabilitation; interim
- PROPOSED RULES**  
16518 Mortgage and loan insurance programs: Cooperative housing mortgage insurance subordinated Secretary-held mortgages; unsubsidized multifamily rental housing projects; conversion; correction
- Immigration and Naturalization Service**  
**RULES**  
16457 Transportation line contracts: AIRCAL, Inc.
- Indian Affairs Bureau**  
**NOTICES**  
16564 Environmental statements; availability, etc.: Hoopa Valley Indian Reservation, CA
- Interior Department**  
*See* Fish and Wildlife Service; Indian Affairs Bureau; Land Management Bureau; Minerals Management Service; Surface Mining Reclamation and Enforcement Office.
- International Trade Administration**  
**RULES**  
16468 Export licensing: Commodity control list; software and electronic computers
- NOTICES**  
16529 Antidumping: Steel reinforcing bars from Canada
- Interstate Commerce Commission**  
**NOTICES**  
Motor carriers:  
16566 Compensated intercorporate hauling operations; intent to engage in  
Railroad services abandonment:  
16566 Burlington Northern Railroad Co.  
16567 Missouri Pacific Railroad Co.  
16567 Southern Pacific Transportation Co.
- Justice Department**  
*See also* Immigration and Naturalization Service.
- NOTICES**  
16567 Pollution control; consent judgments: Plastics Universal Corp, et al.
- Labor Department**  
*See also* Employment and Training Administration; Employment Standards Administration.
- NOTICES**  
16569 Agency information collection activities under OMB review
- Land Management Bureau**  
**NOTICES**  
Exchange of lands:  
16565 California  
Meetings:  
16565 Worland District Grazing Advisory Board
- Legal Services Corporation**  
**NOTICES**  
16579 Meetings; Sunshine Act
- Mexico and United States, International Boundary and Water Commission**  
**NOTICES**  
16569 Environmental statements; availability, etc.: Tijuana-San Diego Area; treatment and disposal facilities for border sanitation problem solution
- Minerals Management Service**  
**NOTICES**  
Outer Continental Shelf; development operations coordination:  
16565 Louisiana Land & Exploration Co.
- Minority Business Development Agency**  
**NOTICES**  
16529 Financial assistance application announcements: Arizona
- National Credit Union Administration**  
**RULES**  
16462 Federal credit unions: Insurance and group purchasing activities
- National Institutes of Health**  
**NOTICES**  
Meetings:  
16560 Animal Resources Review Committee  
16563 National Arthritis Advisory Board  
16560, 16561, 16564 National Cancer Institute (3 documents)  
16561, 16562 National Eye Institute (2 documents)  
16562 National Heart, Lung, and Blood Institute  
16563 National Institute of Allergy and Infectious Diseases  
16562, 16563 National Institute on Aging (2 documents)  
16559 Research Grants Division study sections
- Procurement:**  
16563 Commercial or industrial activities, performance; review schedule [OMB A-76 implementation]
- National Science Foundation**  
**NOTICES**  
Meetings:  
16571 Cell Biology Advisory Panel  
16572 Developmental Biology Advisory Panel  
16571 Geography and Regional Science Advisory Panel  
16570 International Programs Advisory Committee



- 16571 Memory and Cognitive Processes Advisory Panel  
16571 Ocean Sciences Advisory Committee

#### Navy Department

##### NOTICES

##### Meetings:

- 16532 Chief of Naval Operations Executive Panel  
Advisory Committee  
16532 Naval Research Advisory Committee  
16532 Navy Resale System Advisory Committee

#### Nuclear Regulatory Commission

##### PROPOSED RULES

Production and utilization facilities, domestic licensing:

- 16506 Specific exemptions; clarification of standards

##### NOTICES

Applications, etc.:

- 16572 General Public Utilities Nuclear Corp.  
16574 Tennessee Valley Authority  
Environmental statements; availability, etc.:  
16572 General Public Utilities Nuclear Corp.  
16573 Pacific Gas & Electric Co.

#### Occupational Safety and Health Review Commission

##### RULES

Procedure rules:

- 16474 Issuance of subpoenas and failure of parties to file briefs

#### Patent and Trademark Office

##### NOTICES

- 16530 Mask works of Japanese Nationals domiciliaries and sovereign authorities; interim protection; inquiry; hearing date rescheduled

#### Postal Service

##### NOTICES

- 16580 Meetings; Sunshine Act

#### Securities and Exchange Commission

##### NOTICES

- 16580 Meetings; Sunshine Act

#### Small Business Administration

##### NOTICES

- 16576 Agency information collection activities under OMB review  
License surrenders:  
16576 Certco Capital Corp.

#### Surface Mining Reclamation and Enforcement Office

##### PROPOSED RULES

Permanent program submission:

- 16518 Oklahoma

#### Trade Representative, Office of United States

##### NOTICES

Generalized System of Preferences:

- 16578 Articles eligible for duty-free treatment, etc. (trade in civil aircraft)

#### Transportation Department

See also Federal Aviation Administration; Federal Highway Administration.

##### NOTICES

- 16576 Aviation proceedings; certificates of public convenience and necessity and foreign air carrier permits; weekly applications

#### Treasury Department

See also Customs Service.

##### NOTICES

- 16577 Agency information collection activities under OMB review

#### United States Information Agency

##### NOTICES

Grants; availability, etc.:

- 16578 International educational and cultural activities; correction

#### Western Area Power Administration

##### NOTICES

Environmental statements; availability, etc.:

- 16538 Intertie transmission line, CA and OR

#### Separate Parts in This Issue

##### Part II

- 16606 Department of Labor, Employment Standards Administration, Wage and Hour Division

##### Part III

- 16612 Department of Housing and Urban Development, Office of the Assistant Secretary for Housing—Federal Housing Commissioner

##### Part IV

- 16636 Department of Health and Human Services, Food and Drug Administration

##### Part V

- 16672 Department of Education

##### Part VI

- 16680 Department of the Interior, Fish and Wildlife Service

#### Reader Aids

Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.



## CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

<b>3 CFR</b>	358.....	16672
Proclamations:	359.....	16672
5326.....	16449	
<b>7 CFR</b>		
910.....	16451	
981.....	16451	
1004.....	16452	
1427.....	16453	
1980.....	16455	
Proposed Rules:		
400.....	16502	
1421.....	16504	
<b>8 CFR</b>		
238.....	16457	
<b>9 CFR</b>		
3.....	16457	
92.....	16458	
<b>10 CFR</b>		
Proposed Rules:		
50.....	16506	
<b>12 CFR</b>		
563.....	16459	
721.....	16462	
<b>14 CFR</b>		
39 (3 documents).....	16465,	
	16466	
71 (2 documents).....	16466	
75.....	16466	
97.....	16467	
Proposed Rules:		
39 (2 documents).....	16511,	
	16514	
<b>15 CFR</b>		
379.....	16468	
399.....	16468	
<b>20 CFR</b>		
629.....	16473	
<b>21 CFR</b>		
10.....	16636	
25.....	16636	
71.....	16636	
170.....	16636	
171.....	16636	
312.....	16636	
314.....	16636	
511.....	16636	
514.....	16636	
570.....	16636	
601.....	16636	
660.....	16474	
812.....	16636	
813.....	16636	
861.....	16636	
<b>23 CFR</b>		
Proposed Rules:		
625.....	16515	
655.....	16515	
<b>24 CFR</b>		
888.....	16612	
Proposed Rules:		
207.....	16518	
<b>29 CFR</b>		
2200.....	16474	
<b>30 CFR</b>		
Proposed Rules:		
936.....	16518	
<b>34 CFR</b>		
350.....	16672	
352.....	16672	







# Presidential Documents

Title 3—

The President

Proclamation 5326 of April 23, 1985

## National Defense Transportation Day and National Transportation Week, 1985

By the President of the United States of America

### A Proclamation

Our Nation's history can be traced through the development and growth of transportation in America. Our country has grown as transportation has given us access to new geographic, economic, and technical frontiers.

During colonial days, Americans were dependent on the river systems and ocean ports still used in commerce today. President Thomas Jefferson commissioned Lewis and Clark to explore the West through our rivers, providing new opportunities for trade and commerce. In 1825, the Erie Canal, connecting Buffalo to New York, opened the Great Lakes for settlement and industry.

Pioneers broke new ground to the West by way of the Cumberland Road in 1811. Other highways were soon developed to move people and goods across the wilderness. Completion of the first transcontinental railroad in 1869 joined East to West, ushering in a new era of transportation, strengthening American commerce.

Aviation history was made at Kitty Hawk in 1903, launching an aviation system now serving over 300 million passengers a year. Today, we are witnessing the beginning of a new era in space transportation with the development of commercial space vehicles.

As our cities grew, transit systems evolved to provide affordable, convenient urban transportation. The 20th Century brought the automobile, truck, intercity bus, rapid rail systems, and an expanded road system that now includes thousands of miles of interstate highways.

As has been true throughout our history, transportation today is critical to our economy and necessary to our defense. America's transportation systems have made our society the most mobile on earth. A diverse transportation network has assured the rapid, safe, and dependable movement of people and goods throughout the country and around the world.

In recognition of transportation's importance, and to honor the millions of Americans who serve and supply our transportation needs, the Congress, by joint resolution approved May 16, 1957, has requested that the third Friday in May of each year be designated as National Defense Transportation Day; and by joint resolution approved May 14, 1962, that the week in which that Friday falls be proclaimed National Transportation Week.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby designate Friday, May 17, 1985, as National Defense Transportation Day and the week beginning May 12, 1985, through May 18, 1985, as National Transportation Week. I urge the people of the United States to observe these occasions with appropriate ceremonies that will give full recognition to the importance of our transportation system to this country.



IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of April, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and ninth.

Ronald Reagan

[FR Doc. 85-10244

Filed 4-24-85; 11:33 am]

Billing code 3195-01-M



# Rules and Regulations

Federal Register

Vol. 50, No. 81

Friday, April 26, 1985

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 910

[Lemon Reg. 513; Lemon Reg. 512, Amdt. 1]

#### Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

**SUMMARY:** This action establishes the quantity of fresh California-Arizona lemons that may be shipped to the fresh market at 300,000 cartons during the period April 28-May 4, 1985, and increases the quantity of lemons that may be shipped to 310,000 cartons during the period April 21-April 27, 1985. Such action is needed to provide for orderly marketing of fresh lemons for such periods due to the marketing situation confronting the lemon industry.

**DATES:** The regulation (§ 910.813) becomes effective April 28, 1985, and the amendment (§ 910.812) is effective for the period April 21-April 27, 1985.

#### FOR FURTHER INFORMATION

**CONTACT:** William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202-447-5975.

**SUPPLEMENTARY INFORMATION:** This final rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This final rule is issued under Marketing Order No. 910, as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act

of 1937, as amended (7 U.S.C. 601-674). This action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy currently in effect. The committee met publicly on April 23, 1985, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified weeks. The committee reports that lemon demand has improved and should continue to improve all sizes of fruit.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the *Federal Register* (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

#### List of Subjects in 7 CFR Part 910

Marketing Agreements and Orders, California, Arizona, Lemons.

#### PART 910—[AMENDED]

1. Section 910.813 is added to read as follows:

#### § 910.813 Lemon Regulation 513.

The quantity of lemons grown in California and Arizona which may be handled during the period April 28, 1985, through May 4, 1985, is established at 300,000 cartons.

2. Section 910.812 Lemon Regulation 512 is revised to read as follows:

#### § 910.812 Lemon Regulation 512.

The quantity of lemons grown in California and Arizona which may be handled during the period April 21, 1985, through April 27, 1985, is established at 310,000 cartons.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: April 24, 1985.

Thomas R. Clark,

Deputy Director, Fruit and Vegetable Division  
Agricultural Marketing Service.

[FR Doc. 85-10305 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-02-M

#### 7 CFR Part 981

#### Handling of Almonds Grown in California; Administrative Rules and Regulations Governing Crediting for Marketing Promotion

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

**SUMMARY:** This final rule amends one paragraph of the creditable marketing promotion provisions of the administrative rules and regulations established under the Federal marketing order for California almonds. This change is designed to provide handlers with more flexibility in promoting the sale of California almonds.

**EFFECTIVE DATE:** April 26, 1985.

#### FOR FURTHER INFORMATION CONTACT:

Frank M. Grasberger, Acting Chief, Specialty Crops Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250 (202) 447-5053.

**SUPPLEMENTARY INFORMATION:** This final rule has been reviewed under USDA guidelines implementing Executive Order 12291 and Secretary's Memorandum No. 1512-1 and has been classified a "non-major" rule under criteria contained therein.

William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

It is found that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* (5 U.S.C. 553) in that: (1) It gives handlers enough time to plan advertising and promotion



operations by the June 30 deadline; (2) handlers are aware of the action which is a relaxation of previous restrictions; and (3) no useful purpose would be served by delaying the effective date of this action.

Notice of this action was published in the March 22, 1985, issue of the *Federal Register* (50 FR 11510), and interested persons were afforded an opportunity to submit written comments. No comments were received. However, two additional changes in § 981.441(c)(3)(ii) and (iii) were proposed that are not included in this final rule because the Board recommended the comment period be extended to allow the Board time to further review and consider them. Extension of that time will be dealt with in another action.

This final rule revises § 981.441(b) of Subpart—Administrative Rules and Regulations (7 CFR 981.401—981.474; 49 FR 19798; and 40788). Section 981.441 is issued under § 981.41 of the marketing agreement and Order No. 981 (7 CFR Part 981), both as amended, regulating the handling of almonds grown in California and hereinafter referred to collectively as the "order". The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposal is based on a unanimous recommendation of the Almond Board of California, hereinafter referred to as the "Board", which works with USDA in administering the order.

Section 981.41 of the order provides that the Board, with the approval of the Secretary, may allow handlers to receive credit for their direct marketing promotion expenditures, including paid advertising, against their pro rata expense assessment obligations for such activities. Section 981.441 prescribes the rules and regulations which handlers must follow to obtain such credit.

Section 981.441(b) currently provides that in order for a handler to receive credit, his/her paid advertisements must be published, broadcast, or displayed, and his/her other marketing promotion activities must be conducted, during the year for which credit is requested, except that a handler may expend a maximum of 20 percent of his/her total creditable advertising and promotion obligation (as of the June 30 redetermination report) for advertisement published, broadcast, or displayed, and other marketing promotion activities conducted, during the subsequent July 1–December 31 period. A handler utilizing this extension of time must certify to the Board, at the time of the June 30 redetermination, his/her planned expenditures during the extension period and must file any

required documentation with the Board no later than the following January 31.

The Board believes that the 20 percent limit on credit for paid advertising and other marketing promotion activities during the July 1–December 31 extension period is too restrictive and proposed that this limit be increased to 40 percent. A handler's pro rata expense assessment obligation for a particular crop year may not match his/her advertising and promotion needs for that year. Thus, it is desirable to allow a greater portion of a handler's creditable advertising to be carried over from one crop year to the next so that handlers can more effectively utilize their promotion funds.

#### List of Subjects in 7 CFR Part 981

Marketing agreements and orders, Almonds, and California.

#### PART 981—[AMENDED]

Therefore, § 981.441 of Subpart—Administrative Rules and Regulations (7 CFR 981.401–981.474; 49 FR 19798; and 40788) is changed as follows:

##### § 981.441 [Amended]

1. Section 981.441(b) is amended by changing "20 percent" to "40 percent." (Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: April 23, 1985.

Thomas R. Clark,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 85–10174 Filed 4–25–85; 8:45 am]

BILLING CODE 3410–02–M

#### 7 CFR Part 1004

[Docket No. AO–160–A62–R03]

#### Milk in the Middle Atlantic Marketing Area; Order Amending Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

**SUMMARY:** This action amends the "plant" and "pool plant" definitions of the Middle Atlantic order. These changes will allow a federation of cooperatives to qualify its reserve processing plant as a separate pool plant under certain circumstances and to efficiently exchange by-products by pipeline with an adjacent nonpool plant. Such changes are based on evidence presented at a public hearing held in Alexandria, Virginia, on September 13, 1984. The amendments are needed to recognize the changes in marketing conditions. The hearing on this issue was requested by a federation of

cooperatives, which represents a number of dairy farmers who supply milk to the market. Cooperative associations representing more than the required two-thirds of the producers supplying milk for the market during the representative period of December 1984 have approved issuance of the amended order.

**EFFECTIVE DATE:** June 1, 1985.

#### FOR FURTHER INFORMATION

**CONTACT:** Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250, (202) 447–7183.

**SUPPLEMENTARY INFORMATION:** Prior documents in this proceeding:

Notice of Hearing: Issued August 30, 1984; published September 6, 1984 (49 FR 35100).

Emergency Partial Final Decision: Issued October 17, 1984; published October 24, 1984 (49 FR 42737).

Order Amending Order: Issued November 6, 1984; published November 14, 1984 (49 FR 44986).

Recommended Decision: Issued January 29, 1985; published February 1, 1985 (50 FR 4694).

Final Decision: Issued March 22, 1985; published April 1, 1985 (50 FR 12813).

#### Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the Middle Atlantic order was first issued and when it was amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Middle Atlantic marketing area.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the



price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing area; and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as hereby amended regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

(b) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in Sec. 8c (9) of the Act) of more than 50 percent of the milk, which is marketed within the marketing area, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of this order amending the order is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the order as hereby amended; and

(3) The issuance of the order amending the order is approved or favored by at least two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the marketing area.

#### List of Subjects in 7 CFR Part 1004

Milk marketing order, Milk, Dairy products.

#### Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, the handling of milk in the Middle Atlantic marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, as follows:

#### PART 1004—MILK IN THE MIDDLE ATLANTIC MARKETING AREA

1. Section 1004.4 is revised to read as follows:

##### § 1004.4 Plant.

Except as specifically provided in § 1004.7(d)(2), "plant" means the land and buildings together with their surroundings, facilities and equipment, whether owned or operated by one or more persons, constituting a single operating unit or establishment for the receiving, processing or packaging of

milk or milk products (including filled milk). However, a separate facility used only for the purpose of transferring bulk milk from one tank truck to another tank truck or only as a distribution depot for fluid milk products in transit for route distribution shall not be included under this definition.

2. In § 1004.7, paragraphs (d)(2), and (e) are revised to read as follows:

##### § 1004.7 Pool Plant.

(d) \* \* \*

(2) A reserve processing plant operated by a federation of cooperative associations if, during the month, 30 percent or more of the producer milk of member producers of such cooperatives is caused to be delivered to and physically received at pool plants qualified pursuant to paragraph (a) of this section either from the farms of such producers or by transfer in the form of fluid milk products (except filled milk) from the plant(s) of such cooperatives. If a pipeline is maintained between a reserve processing plant and a nonpool plant operated by another person and located on the same premises, the reserve processing plant shall be a pool plant for the month if the operator of such plant proves to the satisfaction of the market administrator that such plant should be eligible for pool status on the basis of the plant's monthly receipts and disposition of milk and that the pipeline was used only to move by-products (not milk) between such plants during the month.

(e) A plant that qualified as a pool plant pursuant to paragraph (b) or (d) of this section during each of the immediately preceding months of September through February shall be qualified for automatic pool plant status for each of the following months of March through August, unless the plant operator files a written request with the market administrator prior to the beginning of any such month asking that such plant not be a pool plant. Such nonpool status shall be effective on the first day of the month following the receipt of such request and shall continue until the plant again qualifies as a pool plant pursuant to paragraph (b) or (d) of this section, subject to the following conditions:

(1) The automatic pool plant status for any plant identified in paragraph (e) of this section shall be cancelled if another plant is qualified as a pool plant on the basis of deliveries to the same plants through which such automatic pooling status was acquired by the plant. Cancellation of the plant's automatic pool plant status shall be effective on

the first day of the month in which the other plant is qualified as a pool plant and shall continue until the plant again qualifies as a pool plant pursuant to paragraph (b) or (d) of this section; and

(2) The automatic pool plant status of a reserve processing plant operated by a federation of cooperative associations qualified pursuant to paragraph (d)(2) of this section shall be forfeited for any month during the March through August period in which the market administrator determines on the basis of the investigation conducted pursuant to paragraph (d)(2) of this section that such plant shall not be a pool plant for the month.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Effective date: June 1, 1985.

Signed at Washington, D.C. on: April 19, 1985.

Karen Darling,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 85-10107 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-02-M

#### Commodity Credit Corporation

##### 7 CFR Part 1427

[Amdt. 3]

#### Standards for Approval of Warehouses for Cotton or Cotton Linters

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

**SUMMARY:** The purpose of this rule is to amend the regulations found at 7 CFR 1427.1081 *et seq.* relating to the Commodity Credit Corporation (CCC) Standards for Approval of Warehouses for Cotton or Cotton Linters. The final rule will: (1) Permit a parent company to submit a financial statement for a wholly-owned subsidiary; (2) permit warehousemen to submit financial statements on forms other than on Form WA-51; (3) revise the references to CCC regulations governing suspension and debarment; (4) permit CCC to accept an irrevocable letter of credit on forms other than Form CCC-33A; (5) delete the use of a Certificate of Competency issued by the Small Business Administration for a warehouseman who is deficient in net worth; (6) delete certain references to the withdrawal of approval of warehouses by CCC; and (7) make certain other miscellaneous changes.



**EFFECTIVE DATE:** April 26, 1985.

**FOR FURTHER INFORMATION CONTACT:**

Lynn W. Howe, 202-447-5785, Warehouse Division, U.S. Department of Agriculture, Agricultural Stabilization and Conservation Service, P.O. Box 2415, Washington, D.C. 20013.

**SUPPLEMENTARY INFORMATION:** This final rule has been reviewed under USDA procedures required by Executive Order 12291 and Departmental Regulation 1512-1 and has been classified "not major" since it does not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environment Assessment nor an Environmental Impact Statement is needed.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 28115 (June 24, 1983).

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of rulemaking with respect to the subject matter of this rule.

The Commodity Credit Corporation Charter Act (15 U.S.C. 714) authorizes CCC to conduct various activities to stabilize, support, and protect farm income and prices. CCC is authorized to carry out such activities as making price support available with respect to various agricultural commodities, removing and disposing of surplus agricultural commodities, exporting or aiding in the exportation of agricultural commodities, and procuring agricultural commodities for sale both in the domestic market and abroad.

Section 4(h) of the CCC Charter Act provides that the Corporation shall not acquire real property in order to provide storage facilities for agricultural commodities, unless CCC determines that private facilities for the storage of

such commodities are inadequate. Further, section 5 of the CCC Charter Act provides that, in carrying out the Corporation's purchasing and selling operations, and in the warehousing, transporting, processing, or handling of agricultural commodities, CCC is directed to use, to the maximum extent practicable, the usual and customary channels, facilities, and arrangements of trade and commerce.

Accordingly, CCC has set forth Standards for Approval of Warehouses for Cotton and Cotton Linters which must be met by warehousemen before CCC will enter into storage agreements with such warehousemen for the storage of cotton which is owned by CCC or which is serving as collateral for CCC price support loans.

During the past few years changes in the cotton warehousing industry, financial institution requirements, and Federal contracting requirements necessitate updating the Standards for Approval of Warehouses for Cotton and Cotton Linters.

Accordingly, a notice of proposed rulemaking was published by the Department in the Federal Register on August 31, 1984, 49 FR 34511, requesting comments with respect to a number of proposals regarding changes in the Standards for Approval of Warehouses for Cotton and Cotton Linters. The comment period was for sixty days and ended on October 30, 1984.

Amendments to the regulations were proposed which would: (1) Permit a parent company to submit a financial statement for a wholly-owned subsidiary; (2) permit warehouses to submit financial statements on forms other than on Form TW-51; (3) incorporate for CCC purposes USDA regulations governing suspension and debarment; (4) permit CCC to accept an irrevocable letter of credit on forms other than Form CCC-33A; (5) delete the use of a Certificate of Competency issued by the Small Business Administration for a warehouseman who is deficient in net worth; (6) delete certain references to the withdrawal of approval of warehouses by CCC; and (7) make certain other miscellaneous changes.

No comments were received concerning the proposed rule. Accordingly, it has been determined that the provisions of the proposed rule should be adopted as a final rule except for minor technical changes. These changes are in §§ 1427.1082(c)(2) and 1427.1086(c)(2) to delete references to Department of Agriculture suspension and debarment regulations and insert in lieu thereof references to suspension and debarment regulations. Subsequent

to the promulgation of the proposed rule, the CCC suspension and debarment regulations were amended to incorporate, with limited exceptions, the Department of Agriculture suspension and debarment regulations. In addition, § 1427.1081 has been revised to change the form number for the financial statement from "TW-51" to "WA-51". It is believed that these minor changes in references from the proposed rule are not of such a nature as to warrant any further public rulemaking.

**List of Subjects in 7 CFR Part 1427**

Cotton, Loan programs—Agriculture, Packaging, and Containers, Price support programs, Surety bonds, and Warehouse.

**Final Rule**

**PART 1427—[AMENDED]**

The provisions of 7 CFR Part 1427 are amended as follows:

1. The authority citation for 7 CFR Part 1427, Subpart—Standards for Approval of Warehouses for Cotton or Cotton Linters is revised to read as follows:

Authority: Secs. 4 and 5, 62 Stat. 1070, as amended, 1072, as amended (15 U.S.C. 714 b and c).

2. In Section 1427.1081, paragraphs (b) and (d)(2) are revised to read as follows:

**§ 1427.1081 General statement and administration.**

(b) Copies of the CCC storage agreement and forms required for obtaining approval under this subpart may be obtained from the Kansas City Commodity Office, U.S. Department of Agriculture, P.O. Box 205, Kansas City, Missouri 64141 (hereinafter referred to as the "KCCO").

(d) \* \* \*

(2) A current financial statement on Form WA-51, "Financial Statement", supported by such supplemental schedules as CCC may request.

Financial statements may be submitted on forms other than Form WA-51 with approval of the Director, KCCO, or the Director's designee. Financial statements shall show the financial condition of the warehouseman as of a date no earlier than ninety (90) days prior to the date of the warehouseman's application, or such other date as CCC may prescribe. Additional financial statements shall be furnished annually and at such other times as CCC may require. CCC also may require that financial statements prepared by the warehouseman or by a



public accountant be examined by an independent certified public accountant in accordance with generally accepted auditing standards. Only one financial statement is required for a chain of warehouses owned or operated by a single business entity. If approved by the Director, KCCO, or the Director's designee, the financial statement of a parent company, which includes the financial position of a wholly-owned subsidiary, may be used to meet the CCC standards for approval for the wholly-owned subsidiary.

4. In § 1427.1082, paragraph (c)(2) is revised to read as follows:

**§ 1427.1082 Basic Standards.**

(c) \* \* \*

(2) Be neither suspended nor debarred under applicable CCC suspension and debarment regulations.

5. In § 1427.1083, paragraph (e) is revised to read as follows:

**§ 1427.1083 Bonding Requirements for Net Worth.**

(e) An irrevocable letter of credit may be accepted by CCC in lieu of the required amount of bond coverage provided that the issuing bank is a commercial bank insured by the Federal Deposit Insurance Corporation. Such standby letter of credit shall be on Form CCC-33A, "Irrevocable Letter of Credit", or on such other form as may be specifically approved by the Director, KCCO, or the Director's designee.

**§ 1427.1085 [Amended]**

6. Section 1427.1085 is amended by removing paragraph (b) and by redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

7. Section 1427.1086 is revised to read as follows:

**§ 1427.1086 Approved of warehouse, requests for reconsideration.**

(a) CCC will approve a warehouse if it determines that the warehouse meets the standards set forth in this subpart. CCC will send a notice of approval to the warehouseman. Approval under this subpart, however, does not relieve the warehouseman of the responsibility for performing the warehouseman's obligations under any agreement with CCC or any other agency of the United States.

(b) Except as otherwise provided in this subpart:

(1) CCC will not approve the warehouse if CCC determines that the

warehouse does not meet the standards set forth in this subpart, and

(2) CCC will send any notice of rejection of approval to the warehouseman. This notice will state the cause(s) for such action. Unless the warehouseman or any officials or supervisory employees of the warehouseman are suspended or debarred, CCC will approve the warehouse if the warehouseman establishes that the causes for CCC's rejection of approval have been remedied.

(c) If rejection of approval by CCC is due to the warehouseman's failure to meet the standards set forth:

(1) In § 1427.1082, other than the standard set forth in paragraph (c)(2) thereof, the warehouseman may, at any time after receiving notice of such action, request reconsideration of the action and present to the Director, KCCO, in writing, information in support of such request. The Director shall consider such information in making a determination of notify the warehouseman in writing of such determination. The warehouseman may, if dissatisfied with the Director's determination, obtain a review of the determination and an informal hearing thereon by filing an appeal with the Deputy Administrator, Commodity Operations, Agricultural Stabilization and Conservation Service (hereinafter referred to as "ASCS"). The time of filing appeals, forms for requesting an appeal, nature of the informal hearing, determination and reopening of the hearing shall be as prescribed in the ASCS regulations governing appeals, 7 CFR Part 780. When appealing under such regulations, the warehouseman shall be considered as a "participant"; and

(2) In § 1427.1082(c)(2), the warehouseman's administrative appeal rights with respect to suspension and debarment shall be in accordance with applicable CCC regulations. After expiration of a period of suspension or debarment, a warehouseman may, at any time, apply for approval under this subpart.

8. Section 1427.1088 is added to read as follows:

**§ 1427.1088 OMB Control Numbers Assigned Pursuant to Paperwork Reduction Act.**

The information collection requirements contained in this regulation (7 CFR Part 1427) have been approved by the Office of Management and Budget under provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Numbers 0560-0040, 0560-0074, 0560-0027, and 0560-0059.

Signed at Washington, D.C., on April 23, 1985.

Everett Rank,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 85-10109 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-05-M

**Farmers Home Administration**

**7 CFR Part 1980**

**Business and Industrial Loan Program**

**AGENCY:** Farmers Home Administration, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Farmers Home Administration (FmHA) amends its Business and Industrial (B&I) Loan Program regulations to permit negotiated reductions in interest rates charged on guaranteed loans. This action is necessary because otherwise loan liquidations will result from borrowers' inability to repay loan installments due to interest rates not being compatible with existing market conditions. The effect of this action is to permit the borrower, lender, and holder (if any) to collectively negotiate a reduced interest rate, thereby benefiting the borrower.

**EFFECTIVE DATE:** April 26, 1985.

**FOR FURTHER INFORMATION CONTACT:** Dwight A. Carmon, Loan specialist, Business and Industry Division, FmHA, USDA, 14th and Independence Avenue, S.W., Washington, D.C. 20250. Telephone: (202) 475-3811.

**SUPPLEMENTARY INFORMATION:** This final action has been reviewed under USDA procedures established in Departmental Regulation 1512-1, which implements Executive Order 12291 and has been determined to be "non-major" since the annual effect on the economy is less than \$100 million and there will be no significant increase in costs or prices for consumers, individual industries, organizations, governmental agencies or geographic regions. There will be no significant effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Catalogue of Federal Domestic Assistance Number for Business and Industrial Loans is 10.422.

The activities covered by this final rule are subject to the requirements for intergovernmental consultation as stated in 7 CFR Part 3015 Subpart V, "Intergovernmental Review of



Department of Agriculture Programs and Activities," and FmHA Instruction 1940-J, "Intergovernmental Review of Farmers Home Administration Programs and Activities."

This final action has been reviewed in accordance with FmHA Instruction 1940-G, "Environmental Program." FmHA has determined that this final action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969, Pub. L. 91-90, an Environmental Impact Statement is not required.

This action responds to numerous inquiries addressing the need to adjust interest rates for the mutual accommodations of borrower(s) and lender(s). This final rule defines FmHA's position on the reduction of interest rates so that the borrower, lender and the Government can accommodate to changing market conditions and conditions in the borrower's ability to make loan payments on schedule.

This final rule allows interest to be reduced by collective action by the borrower, lender and holder. It prohibits fixed rates from being changed to variable rates to reduce the interest rate to the borrower unless the variable rate has a ceiling which is less than the original fixed rate. No increase in interest rates will be permitted except under the normal fluctuations for approved variable interest rate loans.

#### Discussion of Comments Received and Final Rule

A proposed rule was published in the Federal Register (49 FR 21547) on May 22, 1984. That proposal provided for a 30-day comment period. Written comments were received from eighteen respondents generally supportive of the proposed rule.

The proposed rule is adopted without change.

#### Section 1980.423 Interest Rates.

##### Paragraph (a)(1).

FmHA added a cross-reference to paragraph (a)(6)(i) of this section to include an exception to the requirement that there will be no floor or ceiling on variable interest rates. There were no unfavorable comments.

##### Paragraph (a)(6).

This paragraph allows the borrower, lender and holder (if any) to collectively negotiate a permanent reduction in the interest rate on their B&I guaranteed loan at anytime during life of the loan upon written agreement by all parties. One respondent commented that the

proposed rule is unclear as to whether a reduced interest rate below the cost of money to the Government when the Government has repurchased would be acceptable or not. The Agency does not feel that the provision is unclear. The provision was included to ensure that the decision official includes the cost of money to the Government as one factor but not the only factor in reaching a decision. Another respondent suggested that interest rate reductions be limited to one per calendar year. The Agency sees no reason to so limit the rule. Greater flexibility is preferred. In certain instances, more than one interest rate reduction in a year may be necessary. Although this result would not be encouraged, the greater flexibility provided by the proposed rule allows for it. Another respondent suggested that interest rate reductions be allowed for a limited time rather than be a permanent reduction. In the Agency's opinion, it is often difficult, if not impossible, to estimate how long a temporary reduction in interest rate would be necessary to alleviate the borrower's problem of being unable to meet the payment. At this time, FmHA prefers to require a permanent reduction since it provides for stability in payment which could only aid the borrower in its operations. This decision can always be reconsidered later.

##### Paragraph (a)(6)(i).

This paragraph allows a fixed rate to be changed to a variable rate only when the variable rate has a ceiling which is less than the original fixed rate. One respondent suggested this paragraph be revised to remove the requirement of a ceiling on the variable rate. This suggestion is rejected because the Agency wishes to assure that any change in a variable rate will not ultimately result in a higher interest rate than when the interest rate was originally fixed. Another respondent suggested that the paragraph be revised to provide that a fixed rate cannot be changed to a variable rate under any circumstance. The Agency sees no reason to adopt this suggestion since a ceiling is placed on a change to a variable rate requiring it be lower than the original fixed rate.

##### Paragraph (a)(6)(ii).

This paragraph provides that the amount of interest claimed cannot exceed that which would have been eligible for claim under the variable interest rate. One respondent recommended this paragraph be removed because the calculation would be confusing. The Agency chooses to adopt the proposed rule without change

because it believes the calculation can be made.

##### Paragraph (a)(6)(iii).

This paragraph provides that the lender is responsible for legal documentation of interest changes by means of a legal attachment to the promissory note. There were no unfavorable comments.

##### Paragraph (a)(7).

This paragraph prohibits any increase in interest rates on B&I guaranteed loans except where variable interest rate notes are in effect. There were no unfavorable comments.

##### Administrative: Paragraphs (a)(6) and (a)(7).

This new paragraph provides for internal tracking of an interest rate change on a B&I guaranteed loan. There were no unfavorable comments.

#### List of Subjects in 7 CFR Part 1980

Loan programs—business and industry, Rural development assistance, Rural areas.

#### PART 1980—[AMENDED]

Accordingly, FmHA amends § 1980.423 of Subpart E of Part 1980, Chapter XVIII, Title 7, Code of Federal Regulations, by revising paragraph (a)(1), by adding paragraphs (a)(6) and (a)(7), and by adding a paragraph entitled "ADMINISTRATIVE," at the end of the Section to read as follows:

#### § 1980.423 Interest rates.

(a) \* \* \*

(1) A variable interest rate must be a rate that is tied to a base rate published periodically in a financial publication specifically agreed to by the lender and borrower. It must rise and fall with the selected base rate, and changes can be made no more often than quarterly. There will be no floor or ceiling on variable interest rates except as specified in paragraph (a)(6)(i) of this section. The lender must incorporate within the variable rate promissory note at loan closing, the provision for adjustment of payment installments coincident with an interest rate adjustment. This will assure that the outstanding principal balance is properly amortized within the prescribed loan maturity to eliminate the possibility of a balloon payment at the end of the loan.

(6) The borrower, lender and holder (if any) may collectively effect a permanent reduction in the interest rate of their B&I guaranteed loan at any time during the



life of the loan upon written agreement by these parties. FmHA must be notified by the lender, in writing, within 10 calendar days of the change. If the guaranteed portion has been repurchased by FmHA, then FmHA is a holder and must affirm or reject interest rate change proposals. When FmHA is a holder, it will concur in such interest rate change only when it is demonstrated to FmHA that the change is a more viable alternative than initiating or proceeding with liquidation of the loan or continuing with the loan in its present state, and that the Government's financial interests are not adversely affected. Factors which will be considered in making such a determination will include whether the proposed interest rate will be below the Government's cost of borrowing money, whether continuing with the loan would realistically promote or enhance rural development and employment in rural areas, whether the monetary recovery would be increased by proceeding immediately to liquidation, if applicable, or allowing the borrower to continue at a reduced interest rate, and whether an in-depth financial analysis by the lender reasonably indicates that the business would be successful at a lower interest rate and reasonably indicates that the borrower could make the reduced payment and pay off amounts in arrears, if any. The FmHA file will reflect the documentation of the interest rate change decision.

(i) Fixed rates cannot be changed to variable rates to reduce the interest rate to the borrower unless the variable rate has a ceiling which is less than the original fixed rate.

(ii) Variable rates can be changed to reduced fixed rates. In a final loss settlement, when qualifying rate changes were made with the required written agreements and notification, the interest will be calculated for the periods the given rates were in effect, except that interest claimed on a loan which originated at a variable rate can never exceed the amount which would have been eligible for claim had the variable interest remained in force. The lesser cost to the Government will always prevail. The lender must maintain records which adequately document the accrued interest claimed.

(iii) The lender is responsible for the legal documentation of interest changes by an allonge attached to the promissory note(s) or any other legally effective amendment of the rate(s); however, no new note(s) may be issued.

(7) No increases in interest rates will be permitted under the B&I loan guarantee except the normal

fluctuations in approved variable interest rate loans.

Administrative: Par (a)(6) and (a)(7).

The State Director will notify the Finance Office of any interest rate reduction by using Form FmHA 1980-47, "Guaranteed Loan Borrower Adjustments." The State Director will make corrections to the Rural Community Facility Tracking System (RCFTS) reflecting the interest rate change. The FmHA loan file, as well as the attachments to the copy of the promissory note in the file, will be documented by the State Director to reflect any change in the interest rate.

Authority: 7 [U.S.C. 1989; Order of Secretary of Agriculture, 7 CFR 2.23; Order of Under Secretary for Small Community and Rural Development, 7 CFR 2.70]

Dated: December 26, 1984.

Charles W. Shuman,

Administrator, Farmers Home Administration.

[FR Doc. 85-10299 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-07-M

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

#### 8 CFR Part 238

#### Contracts With Transportation Lines; Addition of AirCal, Inc.

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends the listing of transportation lines which have entered into agreements with the Service for the preinspection of their passengers and crew at locations outside the United States by adding the name of AirCal, Inc.

EFFECTIVE DATE: April 12, 1985.

#### FOR FURTHER INFORMATION CONTACT:

Loretta J. Shogren, Director, Policy Directives and Instructions, Immigration and Naturalization Service, 425 I Street, N.W., Washington, DC 20536, Telephone: (202) 633-3048.

SUPPLEMENTARY INFORMATION: The Commissioner of Immigration and Naturalization entered into agreement with AirCal, Inc. to provide for the preinspection of their passengers and crew as provided by section 238(b) of the Immigration and Nationality Act, as

amended (8 U.S.C. 1228(b)). Preinspection outside the United States facilitates processing passengers and crew upon arrival at a U.S. port of entry and is a convenience to the traveling public.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because the amendment merely adds transportation lines' names to the present listing and is editorial in nature.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

#### List of Subjects in 8 CFR Part 238

Aliens, Common carriers, Government contracts, Inspections, Transportation lines.

Accordingly, Chapter I of Title 8 of the Code of Federal Regulations is amended as follows:

### PART 238—CONTRACTS WITH TRANSPORTATION LINES

#### § 238.4 [Amended]

Section 238.4 is amended by adding the name AirCal, Inc. under "At Vancouver."

(Secs. 103 and 238 of the Immigration and Nationality Act, as amended; (8 U.S.C. 1103 and 1228))

Dated: April 22, 1985.

Andrew J. Carmichael, Jr.,

Associate Commissioner, Examinations, Immigration and Naturalization Service.

[FR Doc. 85-10191 Filed 4-25-85; 8:45 am]

BILLING CODE 4410-10-M

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 3

#### Animal Welfare; Marine Mammals

#### CFR Correction

In the January 1, 1985 revision of Title 9 (Parts 1 to 199) of the Code of Federal Regulations, the second formula of § 3.104(b)(3)(i) is incorrect. A correction appearing at 49 FR 27922, July 9, 1984 was not included in the CFR book. The second formula in paragraph (b)(3)(i) of § 3.104 should read as set forth below.

$$\text{Volume} = \frac{(\text{Average Adult Length})^2}{2} \times 3.14 \times \text{depth.}$$

BILLING CODE 1505-02-M



## 9 CFR Part 92

(Docket No. 85-004)

**Semen of Ruminants or Swine From Countries Where Rinderpest or Foot-and-Mouth Disease Exists****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Affirmation of interim rule.

**SUMMARY:** This document affirms, with certain changes, the interim rule which amended the regulations concerning the importation into the United States of semen of ruminants or swine from countries where rinderpest or foot-and-mouth disease exists. The regulations were amended by changing the criteria for testing for foot-and-mouth disease and other infectious diseases in donor animals, by changing the criteria for determining which animals are eligible to be donor animals, and by changing provisions concerning the holding of the semen prior to the completion of the testing. These amendments are necessary to increase the reliability of testing for foot-and-mouth disease and other infectious diseases in the donor animals, and for relieving unnecessary restrictions on the importation of their semen.

**EFFECTIVE DATE:** April 26, 1985.**FOR FURTHER INFORMATION CONTACT:**

Dr. H. A. Kryder, Import-Export Animals and Products Staff, VS, APHIS, USDA, Room 839, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8530.

**SUPPLEMENTARY INFORMATION:****Background**

The regulations in 9 CFR 92.4(d) (referred to below as the regulations) contain specific provisions concerning the importation into the United States of semen of ruminants or swine from countries where rinderpest or foot-and-mouth disease exists.

An interim rule published in the *Federal Register* on November 2, 1984 (49 FR 44088-44090), amended the regulations by changing the criteria for testing for foot-and-mouth disease and other infectious diseases in donor animals, by changing the criteria for determining which animals are eligible to be donor animals, and by changing provisions concerning the holding of the semen prior to the completion of the testing.

The document of November 2, 1984,

invited the submission of written comments on or before January 2, 1985. Six comments were received. The comments were from representatives of a foreign government, a university, a zoo, and Federal government agencies. All of these comments have been carefully considered and are discussed below. Except as otherwise explained below, the provisions of the interim rule have been adopted as a final rule.

**Semen Sample**

Under the provisions of the interim rule, a 0.5 ml sample of semen is required to be taken for testing from each semen collection taken from the donor ruminant or swine. Two of the commenters indicated that the semen sample should be smaller, but they did not indicate what size the sample should be. No changes in the regulations are made based on these comments. As stated in the interim rule at 49 FR 44089, a semen sample of no less than "0.5 ml . . . (must be taken) from each collection since 0.5 ml from each semen collection is the amount that is needed for testing."

One commenter apparently asserted that the semen sample for testing should be unprocessed semen without any added substances. It was intended to require that the semen sample be unprocessed semen without any added substances. Changes are made in the regulations to more clearly reflect such intent.

**Antibiotics**

One commenter indicated that the regulations should be amended to require that semen collected from donor animals be treated with antibiotics as a condition of importation. No changes are made based on this comment. The interim rule only concerns the importation of semen of ruminants or swine originating in any country where rinderpest or foot-and-mouth disease exists. Other provisions in 9 CFR Part 92 regulate the importation of semen of ruminants or swine originating in other countries. It is industry practice to treat with antibiotics all semen (other than test samples) of ruminants or swine offered for importation into the United States, regardless of whether rinderpest or foot-and-mouth disease exists in the country of origin. However, the regulations do not currently require that any semen be treated with antibiotics as a condition of importation. Antibiotics

affect bacteria but have no effect on viruses, such as viruses which cause foot-and-mouth disease and rinderpest. Further, the issue of whether semen of ruminants or swine should be treated with antibiotics as a condition of importation is a general issue for all semen of ruminants or swine offered for importation into the United States from any foreign country. The Department is considering whether to have a separate rulemaking proceeding concerning whether semen of ruminants or swine should be required to be treated with antibiotics as a condition of importation.

**Testing for Diseases**

The regulations specifically provide for testing of the donor animal for rinderpest and foot-and-mouth disease. One commenter stated that the donor animal should also "be free of tuberculosis, brucellosis, trichomoniasis, leptospirosis, and vibriosis." No changes are made based on this comment. The regulations already provide for testing as necessary to ensure that the donor animal is free of communicable diseases, including any testing necessary to ensure that the donor animal is free of the diseases specified in the comment.

**FMD-Vaccinated Donor Bulls**

One commenter expressed concern about the "use of FMD-vaccinated donor bulls." This issue was dealt with at some length in the document of November 2, 1984. It was stated on page 44089 of that document that:

This document deletes the virus neutralization and the fluorescent antibody tests for FMD for ruminants, and changes the regulations to provide instead that the blood samples from ruminants shall be tested for FMD antibodies using the virus infection associated (VIA) test, and to provide that the [oesophageal-pharyngeal] samples from ruminants shall be tested for FMD virus using the virus isolation test. . . .

Prior to the effective date of this document, the semen from donor ruminants was required to have come from ruminants that had not been vaccinated against [foot-and-mouth disease]. The new testing protocol for ruminants is sufficiently sensitive to distinguish between the serological response produced by the presence of FMD and the serological response produced by FMD vaccine. Therefore, the requirement that the semen must come from a donor ruminant that has not been vaccinated against FMD is no longer necessary, and is deleted. . . .



The Department reaffirms this rationale, and no changes are made in the regulations concerning this issue.

#### Exotic Ruminants in the Wild

One commenter questioned whether the regulations apply to the importation of semen from exotic ruminants in the wild. The regulations apply to the importation of "semen of ruminants or swine, originating in any country designated in paragraph (a) of § 94.1 of this subchapter as a country where rinderpest or foot-and-mouth disease is determined to exist." This includes any ruminants regardless of whether they are exotic ruminants in the wild.

#### Laboratory

The regulations previously provided for semen testing and other testing to be performed at the Plum Island Animal Disease Laboratory. The actual name of the laboratory is the "Foreign Animal Disease Diagnostic Laboratory." One commenter asserted that the regulations should use the official name of the laboratory. The Department agrees with the commenter, and the name of the laboratory is changed to "Foreign Animal Disease Diagnostic Laboratory" wherever it appears in § 92.4. In addition, "Greenport, New York" is added after the name to indicate the location of the laboratory.

#### Miscellaneous

Also, in § 92.4(d)(1)(iv) footnote 1 is redesignated as footnote 2.

#### Executive Order 12291 and Regulatory Flexibility Act

This action has been reviewed in conformance with Executive Order 12291 and has been determined to be not a "major rule." The Department has determined that this action will not have an effect on the economy of \$100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; will not have any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

It is anticipated that the amount of semen from ruminants and swine that will be annually imported under the provisions of § 92.4(d) will constitute less than 1 percent of the semen of ruminants and swine annually utilized in the United States. Further, the importation of such semen is not the

primary activity of any business in the United States.

Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### List of Subjects in 9 CFR Part 92

Animal diseases, Canada, Imports, Livestock and livestock products, Mexico, Poultry and poultry products, Quarantine, Transportation, Wildlife.

Accordingly, it has been determined that the interim rule concerning semen of ruminants or swine from countries where rinderpest or foot-and-mouth disease exists (49 FR 44088-44090) is adopted, with the changes shown below, as a final rule.

#### PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

##### § 92.4 [Amended]

1. In § 92.4(d)(1)(ii), "Plum Island Animal Disease Laboratory of the United States Department of Agriculture" is changed to "Foreign Animal Disease Diagnostic Laboratory, Greenport, New York."

2. In § 92.4(d)(1)(iii), "Plum Island Animal Disease Laboratory of the United States Department of Agriculture" is changed to "Foreign Animal Disease Diagnostic Laboratory, Greenport, New York."

3. Footnote 1 in § 92.4(d)(1)(iv) is redesignated footnote 2 and "Plum Island Animal Disease Center," is removed from redesignated footnote 2.

4. In § 92.4(d)(4), "Plum Island Animal Disease Laboratory of the United States Department of Agriculture" is changed to "Foreign Animal Disease Diagnostic Laboratory, Greenport, New York."

5. In § 92.4(d)(5), the first two sentences are changed to read: "The semen sample from each collection shall have consisted of unprocessed semen without any added substances, and shall have been tested at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York. Such tests shall have been performed by injecting the semen samples into test animals which are susceptible to rinderpest or foot-and-mouth disease."

Authority: Sec. 203, 60 Stat. 1087, as amended; secs. 6, 7, 8, 10, 26 Stat. 416, as amended, 417; sec. 2, 32 Stat. 792, as amended; sec. 308, 46 Stat. 689, as amended; secs. 2, 3, 4, 5, 11; 76 Stat. 129, 130, 132; sec. 1,

84 Stat. 202; 7 U.S.C. 1622, 19 U.S.C. 1306, 21 U.S.C. 302-105, 111, 134a, 134b, 134c, 134d, 134f, and 135; 7 CFR 2.51, and 371.2(d).

Done at Washington, D.C., this 22nd day of April 1985.

Billy G. Johnson,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 85-10030 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-24-M

#### FEDERAL HOME LOAN BANK BOARD

##### 12 CFR Part 563

[No. 85-293]

#### Over-the-Counter Financial Options Trading; Accounting for Financial Options

Dated: April 18, 1985.

**AGENCY:** Federal Home Loan Bank Board.

**ACTION:** Final rule and request for comments.

**SUMMARY:** The Federal Home Loan Bank Board ("Board"), as the operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC" or "Corporation"), is amending its regulations pertaining to financial options transactions by institutions whose accounts are insured by the FSLIC ("insured institutions"). The amendment will permit an insured institution to enter into over-the-counter financial options transactions ("OTC options") with primary dealers in government securities and with those affiliated companies substantially engaged in similar activities, provided that the primary dealer guarantees the transactions entered into by its affiliate. The regulation previously had been interpreted as precluding OTC options, thereby limiting financial options transactions to those traded on designated exchanges. The amendment is intended to reflect the Board's belief that OTC options transactions may be effectively used by insured institutions to hedge their interest-rate risk, and that limiting the counterparty to primary dealers will reduce the credit and liquidity risks associated with these transactions.

The Board also has revised the manner in which an insured institution accounts for "short call" positions (both for exchange-traded and OTC options). The regulation formerly permitted an institution that entered into a short call option matched against a specific asset, liability, or an intended cash-market transaction, to defer any realized losses over the estimated life of the matched



item while recognizing the option commitment fee as income over the term of the option. The amendment is intended to discourage institutions from entering into short call positions to take advantage of the favorable accounting treatment, rather than for sound economic reasons, and to remove an incentive which may make some institutions reluctant to close out their short call positions even when losses are increasing in order to continue to record the commitment fee as income. As amended, the regulation will require that fees received in conjunction with short call options and any related losses be deferred and amortized over the estimated life of the hedged item.

**DATES:** Effective date: April 24, 1985. Comments must be received by: June 24, 1985.

**ADDRESS:** Send comments to Director, Information Services Section, Office of the Secretariat, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, D.C. 20552. Comments will be available for public inspection at the above address.

**FOR FURTHER INFORMATION CONTACT:** Robert J. Pomeranz, Policy Analyst, Office of Policy and Economic Research, (202) 377-6209; Diana Garmus, Financial Analyst, Office of Examination and Supervision, (202) 377-6820, or Robert Monheit, Attorney, Office of General Counsel, (202) 377-6448; Federal Home Loan Bank Board, 1700 G Street, NW., Washington, D.C. 20552.

**SUPPLEMENTARY INFORMATION:** *Over-the-Counter ("OTC") Options Transactions.* The Board has provided by regulation (12 CFR 563.17-5) that an insured institution (to the extent that it has the legal power to do so) may engage in the purchase or sale of financial-options contracts. However, only financial-options contracts based upon a financial instrument that the institution has authority to invest in or issue, designated by the Commodity Futures Trading Commission ("CFTC") or the Securities and Exchange Commission ("SEC"), and under terms and conditions established by an exchange designated or regulated by the CFTC or the SEC, can be used (§ 563.17-5(a)(4) and (c)). As a result, insured institutions were not permitted by this regulation to engage in over-the-counter transactions in financial-options contracts. See: Office of Examination and Supervision, Federal Home Loan Bank Board, T-Memorandum No. T-74.

The Board has further considered the use of OTC options by insured institutions and recognizes that there are certain advantages, as well as risks, inherent in the use of such transactions.

OTC options may be effectively used by insured institutions to hedge or limit their exposure to interest-rate risk. Through these transactions, institutions may reduce the "basis" risk (price and yield correlations between the item hedged and the hedging vehicle) normally associated with hedging balance-sheet items or intended cash-market transactions. Also, while many institutions have invested in government-guaranteed mortgage-backed securities, there are no exchange-traded option contracts based upon these securities. Thus, OTC options may provide needed flexibility for institutions involved in these securities or involved in mortgage-banking operations. OTC options also provide greater flexibility because their terms (such as expiration dates) may be negotiated by the parties.

However, this very lack of standardization and lack of exchange-governed rules may subject participants to substantial credit and liquidity risk. The Board believes that if OTC options transactions between insured institutions and any counterparty were permitted, it would be difficult to determine the creditworthiness of the numerous potential counterparties and the market value of the transaction. As a result, additional reporting, recordkeeping, monitoring and other requirements might be necessary beyond those currently required of insured institutions in connection with exchange-traded options. In addition, the Board might find it necessary to attempt to monitor and exercise some regulatory control over all OTC option counterparties, a task too burdensome for this agency.

Instead, the Board believes that, in light of the potential credit and liquidity risks and after considering possible alternative methods for dealing with such problems, it is both necessary and preferable to limit the counterparties to "primary dealers" in government securities (i.e. members of the Association of Primary Dealers in United States Government Securities). Primary dealers are actively engaged in the distribution of government securities among investors, are substantially capitalized, make continuous markets, have a long-term commitment to the market and the capacity to maintain continuous markets in OTC options. Primary dealers are monitored by the Federal Reserve Bank of New York and must submit daily reports on their market positions as well as monthly financial statements, both used to test their capital adequacy on a daily basis. These reports are supplemented by regular contacts and on-site visits by

representatives of the Federal Reserve Bank of New York. Thus, limiting OTC options counterparties to primary dealers should reduce the credit risk associated with such transactions without the necessity of the Board monitoring the capital adequacy of all potential counterparties. Insured institutions are required to follow the same reporting and recordkeeping requirements for OTC options as for exchange-traded options, and primary dealers must report their OTC option contracts with insured institutions to the Board in order to be eligible to participate in these transactions with the Board's regulatees. The Board appreciates the confidential nature of the information that will be submitted in the reports and has been advised by staff that such information falls within the purview of 5 U.S.C. 552(b) (4) and (8) and thus would be exempt from disclosure under the Freedom of Information Act.

The Board is aware that some primary dealers conduct OTC options trading only through affiliated entities and does not wish to require these primary dealers to restructure their operations in order to become counterparties in OTC options transactions with insured institutions. The Board believes that, because of the primary dealer's capital adequacy, ability to make continuous markets, and continuous monitoring by the Federal Reserve Bank of New York, a guarantee by a primary dealer of the OTC options transactions of its affiliates is sufficient to limit the credit and liquidity risks facing insured institutions. However, the Board is concerned that the affiliates have demonstrated experience in trading government securities, and is limiting the eligible affiliates to those that have substantially engaged in the trading of government securities. Therefore, the Board has included, in the definition of a "primary dealer", any parent, subsidiary, or affiliate that is substantially engaged in dealing in government securities, provided that the primary dealer guarantees the OTC options transactions between its affiliate and any insured institution.

#### Accounting Amendments

The accounting regulation required that the option premium be divided into two components—the immediate exercise value (intrinsic value) and the option commitment fee (time value). If the transaction involves a long put or call, the option commitment fee (paid by the institution) is recognized as an expense over the term of the option. If the transaction involves a short call or



short put, the option commitment fee (received by the institution) is recognized as income over the term of the option. When an option is matched against a specific asset, liability, or an intended cash-market transaction, any realized gains or losses are deferred over the estimated life of the matched item. When an option is unmatched, it must be carried on the books at its immediate exercise value. Unmatched options normally involve short put and long call positions.

These accounting techniques may be abused with respect to short call options. The option commitment fee is determined at the time the position is established and this fee is recognized as income over the term of the option, while any realized losses are deferred over the estimated term of the matched asset. This accounting treatment may cause an institution to enter into short call positions for the accounting treatment rather than for sound economic reasons. Moreover, even when losses are increasing, some institutions may be reluctant to close out their short call positions since they can still record the commitment fee as income. The following are examples demonstrating how these accounting techniques fail to reflect the economics of the transactions.

An institution sells a call option on Treasury bonds with an exercise price of 70 and three months to expiration. The institution receives a \$2,000 option premium. The option is based on a \$100,000 par value, 8% coupon rate, 20-year Treasury bond and the market value of the underlying instrument is 70. If this is a matched option, the entire option commitment fee may be recognized in income over the term of the option regardless of any interest-rate changes. The institution could record monthly income of \$667 for each call option sold (based on a straight-line amortization method).

If interest rates decline and the market value of the underlying instrument increases to 74 at the time the option expires, the option contract would have a value of \$4,000. The commitment fee of \$2,000, received at the inception of the contract, would have been recognized in income while the amount required to offset the option would be deferred over the estimated term of the matched asset. In reality, the institution realized a \$2,000 loss, but recorded income of \$2,000 over the option contract term. It would defer the loss of \$4,000 which will be amortized over the estimated life of the matched asset. If the institution owned the underlying security, the security's

market value would have appreciated by \$4,000 during the three-month period.

If interest rates had increased, so that the market value of the security underlying the option contract had declined to 66, the institution would not have been required to recognize the decline in the current period as long as the cash-market security was held for investment purposes. The loss would be recognized over the life of the security through a lower return on the investment. This result is inconsistent with the recognition of the commitment fee of \$2,000 over the term of the option contract. This accounting does not reflect the economics of the transaction and is exacerbated by the lack of a position limit on short calls.

If the described accounting treatment for short call options were not changed, some institutions would enter into large positions based on the accounting treatment rather than the economics of the transaction. The availability of this technique could also encourage mismanagement of the position. Further, a problem institution could temporarily and artificially bolster its net worth if it enters into short call positions and records the option commitment fee to income, thus hindering the Board's ability to take appropriate supervisory action in a timely fashion.

For these reasons, the Board has determined to amend § 563.17-5(g) to require that option commitment fees received for the sale of matched short call options be recorded as a discount on the matched asset. This fee, together with any related losses from these transactions, will be deferred and amortized over the estimated life of the matched item. This accounting treatment, applicable to such transactions entered into after the effective date of this rule, more closely parallels the concept of hedge accounting, which attempts to match gains and losses from option transactions with those of the matched item. It is also intended to deter insured institutions from entering into short call positions solely for the benefit derived from a more favorable accounting treatment.

#### Solicitation of Comments

The Board finds that observance of the public notice and comment procedures of 5 U.S.C. 553(b) and 12 CFR 508.11 and the 30-day delay of effective date of 5 U.S.C. 553(d) and 12 CFR 508.14 is unnecessary, impracticable and contrary to the public interest. The amendments adopted pertaining to OTC options transactions increase the ability of insured institutions to enter into option

transactions. This portion of the amendments relieves a restriction and the Board finds that it is in the public interest for insured institutions, to the extent permitted by applicable law, to take immediate advantage of the authority to enter into OTC options transactions. The Board also finds that it would be impracticable and contrary to the public interest to delay the amendments pertaining to accounting for matched short call options because insured institutions might be encouraged to enter into the soon-to-be-curtailed transactions during such period in order to take maximum advantage of the old accounting rule, thus threatening safety and soundness. However, the Board solicits comments on both the OTC options authorization and the accounting amendments, and any other changes necessary to ensure that insured institutions engage in options transactions in accordance with safe and sound practices.

#### List of Subjects in 12 CFR Part 563

Savings and loan associations, Savings banks, Securities.

Accordingly, the Federal Home Loan Bank Board hereby amends Part 563, Subchapter D, Chapter V of Title 12, *Code of Federal Regulations*, as set forth below.

#### SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

#### PART 563—OPERATIONS

Amend § 563.17-5 by revising paragraphs (a)(4), (c), (e), and (g) (2) and (3); and by adding a new paragraph (a)(12); as follows:

#### § 563.17-5 Financial options transactions.

(a) *Definitions.* \* \* \*

(4) *Financial options contract.* An agreement to make or take delivery of a standardized financial instrument upon demand by the holder of the contract at any time prior to the expiration date specified in the agreement, under terms and conditions established either by (i) an exchange designated or regulated by the Commodity Futures Exchange Commission or the Securities Exchange Commission, or (ii) the insured institution and a primary dealer in government securities that are counterparties in an over-the-counter transaction.

(12) *Primary dealer in government securities.* Any member of the Association of Primary Dealers in United States Government Securities and any parent, subsidiary, or affiliated entity of such primary dealer: *Provided,*



that the member guarantees (to the satisfaction of the Corporation) the over-the-counter financial options transactions between its parent, subsidiary, or affiliated entity with an insured institution, and *Provided further*, that the parent, subsidiary, or affiliated entity is substantially engaged in similar activities.

(c) *Authorized contracts.* An insured institution may engage in financial options transactions using any financial options contracts either (1) designated by the Commodity Futures Trading Commission or approved by the Securities and Exchange Commission; or (2) entered into with a primary dealer in government securities, and based upon a financial instrument that the institution has authority to invest in or to issue, or based upon a financial futures contract.

(e) *Notification and reporting.* (1) An insured institution shall notify the District Director—Examinations of the Federal Home Loan Bank district in which it is located immediately following authorization of its board of directors to engage in financial options transactions. The institution shall report its outstanding positions together with the total unrealized gain or loss from such positions to the Board.

(2) An insured institution shall not engage in an over-the-counter financial options transaction with any primary dealer unless such primary dealer notifies the District Director—Examinations of the Federal Home Loan Bank district in which the insured institution is located immediately following the entering into such transaction, and reports monthly on the outstanding positions of such insured institution.

(g) *Accounting.*

(2) *Option commitment fee.* (i) The option commitment fee paid for a long position or received from the sale of a short put option shall be amortized to income or expense over the term of the option, except as provided in paragraph (g)(3)(ii) of this section.

(ii) The option commitment fee received from the sale of a matched short call option shall be deferred and treated as a discount on the matched asset. The option commitment fee received from the sale of an unmatched short call option shall be amortized to income over the term of the option.

(3) *Options contracts.* (i) Gains or losses on options contracts that are matched with assets or liabilities carried at the lower of cost or market value or carried at market value shall be

considered in determining the market value of the asset or liability.

(ii) Options positions that are matched with assets or liabilities carried at cost or to be carried at cost shall be accounted for as follows:

(a) If a commitment fee will be or has been received with respect to the matched asset, the option commitment fee shall be treated as an adjustment of such fee. The adjusted commitment fee shall then be treated as a fee paid or received in connection with the matched asset;

(b) If a commitment fee has not been received with respect to a matched asset, the option commitment fee (except if received for the sale of a short call option) shall be amortized to income or expense over the commitment period by the straightline method;

(c) Any resulting gain or loss from an option position shall be treated as a discount or premium on the matched asset or liability;

(d) In the event that the cash-market or forward-commitment position with which an option is matched is sold or will not occur, the option shall be marked to market.

(iii) The immediate exercise value of short puts and other unmatched option positions shall be carried at their current market value.

(Sec. 409, 94 Stat. 160, secs. 402, 403, 407, 48 Stat. 1256, 1257, 1260, as amended (12 U.S.C. 1725, 1726, 1730); sec. 5A, 47 Stat. 727, as amended by sec. 1, 64 Stat. 256, as amended; sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1464), Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943-48 Comp., p. 1071)

By the Federal Home Loan Bank Board,  
Jeff Sconyers,  
Secretary.

[FR Doc. 85-10032 Filed 4-25-85; 8:45 am]

BILLING CODE 6720-01-M

## NATIONAL CREDIT UNION ADMINISTRATION

### 12 CFR PART 721

#### Federal Credit Union Insurance and Group Purchasing Activities

**AGENCY:** National Credit Union  
Administration (NCUA).

**ACTION:** Final rule.

**SUMMARY:** NCUA amends its regulations in order to allow Federal credit unions to receive income in connection with the sale to their members of credit-related insurance and share account-related insurance. Previous rules limited Federal credit unions to receiving reimbursement from the insurances company for the credit union's

administrative costs. The rule is issued with a delayed effective date (August 1, 1985) so that Federal credit unions will have sufficient time to study the effects of and prepare to comply with relevant state insurance laws.

**EFFECTIVE DATE:** August 1, 1985.

**ADDRESS:** National Credit Union  
Administration, 1776 G Street, NW.,  
Washington, D.C. 20456.

**FOR FURTHER INFORMATION CONTACT:**  
Robert M. Fenner, Director, or Hattie M.  
Ulan, Attorney, Department of Legal  
Services at the above address or  
telephone: (202) 357-1030.

#### SUPPLEMENTARY INFORMATION:

##### Background

Part 721 of NCUA's Rules and Regulations authorizes Federal credit union (FCU) participation in insurance and other group purchasing activities, through which insurance and other goods and services are made available from third party vendors to credit union members. Part 721 has two sections. Section 721.1 authorizes FCU's to perform administrative functions for the vendor. Section 721.2 generally limits FCU's to receiving reimbursement for the cost of their involvement in the insurance or group purchasing activity.

In July of 1984, the NCUA Board requested public comment on a proposed change to § 721.2 that would allow FCU's to receive income in excess of cost in connection with the sale of credit-related insurance to members. (See 49 FR 30739, 8/1/84.) The proposal was based in part on NCUA's determination that an FCU may, as a matter of law, be permitted to generate income in connection with an insurance or group purchasing activity that is "incidental" to the exercise of an expressly authorized power (e.g., the power to make loans to members). The Board also requested comment on whether any other insurance or group purchasing activity (in addition to credit-related insurance) may be considered incidental to the exercise of an express power, and if, so, whether § 721.2 should be amended to allow FCU's to generate income from those activities as well.

NCUA received a total of seventy comment letters in response to the proposal. Two credit union trade associations, one insurance underwriter, two insurance trade associations, four state credit union leagues, one state credit union service system, one attorney, eight insurance agencies and forty-five credit unions responded to the proposal. Forty-eight commenters favored removing the reimbursement



restrictions on credit-related insurance and twenty-one commenters were opposed. The majority of the credit unions favored removing the restrictions, while the insurance representatives were generally opposed.

After review of the comments and further consideration of the issues, the Board has determined to remove the reimbursement limits for insurance directly related to extensions of credit and for insurance directly related to the opening and maintenance of share, share certificate and share draft accounts. The following analysis addresses the major issues raised in the proposal and in the comment letters.

#### Analysis

##### Authority

Federal credit unions, like all financial institutions, are institutions of statutorily limited powers. The powers of FCU's are enumerated in section 107 of the Federal Credit Union Act (12 U.S.C. 1757). Included are several specific powers, such as the power to make loans to members, to make certain investments, and to accept share, share draft and share certificate accounts. The various specific powers are followed by the authority "to exercise such incidental powers as shall be necessary or requisite to enable [the FCU] to carry on effectively the business for which it is incorporated." (12 U.S.C. 1757(15).) Prevailing case law construes this "incidental powers" clause to authorize activities that are "convenient or useful in connection with performance of one of [the credit union's] established activities pursuant to its express powers." *American Bankers Association v. Connell*, 447 F. Supp. 296, 298 (D.D.C., 1978).

The NCUA Board has consistently construed the powers of Federal credit unions broadly, in order to afford maximum flexibility to FCU's in providing services to their members. It is clear, however, that a Federal credit union may engage in an insurance or group purchasing activity for the purpose of generating income only if that activity is expressly authorized or is properly incidental to the exercise of an express power. Involvement in "nonincidental" insurance and group purchasing is permitted on a cost reimbursement basis on the theory that the FCU is not engaging in the particular activity or business, but rather is simply providing informational or good-will services to members and receiving reimbursement for the cost of the FCU's involvement.

#### Scope of Rule Change

Consistent with the above analysis, and after review of the comments, the Board has determined to eliminate the reimbursement restrictions for any sale of insurance which is "directly related to an extension of credit by the credit union or directly related to the opening or maintenance of a share, share draft or share certificate account at the credit union." (See § 721.2(b)(2) of the final rule.)

Included among the types of insurance that may be incidental to an extension of credit by an FCU are: credit life insurance, credit disability insurance, loss of income insurance, property and casualty insurance on motor vehicles, boats and residential dwellings, title insurance, mortgage guarantee insurance, and mechanical breakdown insurance on motor vehicles. Life savings insurance is the primary existing example of share-related insurance of which the Board is aware. Most FCU's that offer life savings insurance do so pursuant to a group plan under which the FCU itself pays the premium for all members. Some FCU's have chosen, however, to offer life insurance on a member-pay basis in connection with share, share certificate and share draft accounts. In addition, other credit unions are offering life and disability insurance in connection with IRA accounts.

Federal credit union involvement in other insurance and in group purchasing of other goods and services will continue to be limited to a cost reimbursement basis.

#### Reverse Competition

In its proposal, the Board asked whether reimbursement restrictions should be retained in order to prevent "reverse competition" in the sale of credit insurance. That is, it has previously been suggested that in the absence of reimbursement restrictions, credit unions would seek out insurance paying the highest commission, without due regard for the cost of the insurance to the members. Commenters argued fervently on both sides of the issue. Those who argued that reverse competition exists insisted that lifting the reimbursement cap for credit insurance would increase costs to credit union members while decreasing their benefits. Those in favor of lifting the reimbursement caps argued that reverse competition will not occur in credit unions. Rather, the credit union will have an opportunity to receive income that is presently paid to other parties, and the benefits of increased compensation on credit insurance will

accrue to the credit union members as increased dividends on savings, lower interest rates on loans and/or increased services to members.

The majority of the commenters who argued that reverse competition will develop were not FCU's. In fact, only two FCU commenters expressed the view that reverse competition will become a problem if the reimbursement restrictions on credit insurance are lifted.

While the NCUA Board appreciates the concerns expressed with respect to the potential for reverse competition in the credit insurance market, the Board believes that the ability to prevent such developments can and should properly be placed in the hands of Federal credit unions and Federal credit union management. Credit unions are cooperative member-owned institutions. The entire board of directors is elected by the membership, and thus is continuously accountable to the interests of the member. Moreover, the directors serve as volunteers. Directors and employees are and will continue to be prohibited from personally receiving commissions or other forms of compensation in connection with credit insurance sales (see § 721.2(c) of the regulation). Thus, there is little incentive for a credit union to simply seek out the insurance product paying the highest commissions. To the extent that Federal credit unions do choose to receive commissions or other income, that income should redound to the benefit of the entire membership as discussed above.

Also concerning the issue of whether FCU's should be allowed to receive income, the Board notes that many credit unions now receive commission income indirectly by establishing credit union service organizations that receive the commission income and pay it through to the credit union as a return on the credit union's investment in the service organization. Allowing FCU's the choice of receiving the income directly will recognize what is currently taking place in the marketplace and eliminate the need for the artificial device of establishing a service organization. Finally, with respect to reverse competition, the Board notes that if the evidence at a future date demonstrates that Federal credit union members are paying dramatically higher insurance premiums as a result of the removal of compensation limits, NCUA can and will reconsider this issue.

#### State Insurance Law

As noted in the Board's proposal, Federal credit unions' obligation to



comply with state insurance laws is not affected by a change to NCUA's regulation. It is not NCUA's intent to interfere with the authority and ability of state insurance commissioners to regulate insurance activities. Although FCU's will not be subject to NCUA limits on credit-related and share-related insurance under the new regulation, they are subject to any state regulations on all insurance activities.

For example, most states impose licensing requirements upon entities receiving insurance compensation in excess of cost. A few of the commenters opposed to lifting the reimbursement restrictions stated that the potential licensing requirements will impose too much of a regulatory burden upon FCU's. The Board does not believe this to be the case for two reasons. First, a credit union may choose not to increase the compensation it receives for credit-related and share-related insurance. Federal credit unions that choose to limit their reimbursements to actual costs, or to a cost approximation that is acceptable to the state insurance commission, may not be subject to licensing requirements under state laws. Second, if an FCU receives compensation in excess of costs, the delayed effective date of the new regulation (August 1, 1985) will allow FCU's adequate time to educate themselves as to any licensing or other requirements that apply.

One commenter raised the issue of assignment of insurance commissions. Apparently, in some states a financial institution may not be licensed as an insurance agent. A natural person must be licensed as the agent in order to receive insurance commissions above costs. NCUA will have no objection to an employee or official of the FCU becoming licensed as an insurance agent on the condition that all insurance income received as agent is assigned to the FCU. This can be accomplished through a contractual arrangement between the employee/agent and the FCU.

The FCU must be in compliance with state insurance laws. This includes state laws on licensing, receipt of compensation and insurance-related unfair or deceptive practices. Various methods of receiving insurance compensation may be proper under different state laws. The following is a nonexclusive list of methods which may be available to FCU's:

- an FCU may serve as an insurance agent and receive compensation as such.
- an FCU employee or official may be licensed as an insurance agent and

receive compensation so long as the employee or official assigns all compensation to the FCU.

- an FCU may acquire a group credit insurance policy and provide coverage to its members for loans made to them under such a policy. The FCU may receive experience refunds, dividends or retrospective rate credits from the insurance company as provided in the group policy.
- an FCU may choose not to receive increased compensation available under the new regulation and continue to receive reimbursements for costs.
- an FCU may provide credit- and/or savings-related insurance at no additional charge to its members.

The Board believes that each FCU board of directors should determine which method is appropriate for its FCU and the FCU's members.

#### Compensation to Employees, Officials and Family Members

Very few comments addressed the issue of compensation to officials, employees and their family members. As noted in the proposal, the prohibition on such commissions is a carryover from the present regulation. Several commenters did note that the term "immediate family" should be defined for purposes of this regulation. NCUA has previously defined this term to mean "a spouse, or a child, parent, grandchild, grandparent, brother or sister, or the spouse of any such individual" in both its lending and investment regulations. (See 12 CFR 701.21(c)(8) & 703.2(i) and 703.4(e).) The Board believes that this same definition should apply to Part 721 and has added the definition in the final rule. Although insurance compensation to employees and officials is restricted, an employee or official who is the licensed insurance agent for the FCU may, as previously indicated, receive compensation on the condition that it is assigned in its entirety to the FCU.

#### Effective Date

This final rule will become effective August 1, 1985. The effective date is delayed to provide FCU's adequate time to educate themselves on state laws they may have to comply with under the new regulation.

#### Regulatory Flexibility Act

The NCUA Board hereby certifies that the final rule will not have a significant economic impact on a substantial number of small credit unions because the rule will increase their management flexibility and reduce their paperwork burdens. A Regulatory Flexibility Analysis is, therefore, not required.

#### Financial Regulation Simplification Act

Since this final rule reduces burdens and delay would cause unnecessary harm, the NCUA Board finds that full and separate consideration of all the requirements of the Financial Regulation Simplification Act is impracticable. The NCUA Board has, however, considered most of these policies, as set forth in the preamble above.

#### List of Subjects in 12 CFR Part 721

Credit unions, insurance, Group purchasing.

Dated: April 17, 1985.

Rosemary Brady,  
Secretary of the Board.

Authority: 12 U.S.C. 1757(15); 12 U.S.C. 1766(a).

#### PART 721—[AMENDED]

Accordingly, the NCUA rules and regulations (12 CFR Part 721) are amended as follows:

Section 721.2 is revised to read as follows:

#### § 721.2 Reimbursement.

(a) For purposes of paragraph (b) of this section, the following definitions shall apply:

(1) "Dollar amount" shall mean \$4 per single payment policy, \$6 per combination policy, or \$4 per annum for any other type of policy; and

(2) "Cost amount" shall mean the total of the direct and indirect costs to the Federal credit union of any administrative functions performed on behalf of the vendor. The Federal credit union must be able to justify this amount using standard accounting procedures.

(b) A Federal credit union may be reimbursed or compensated by a vendor for activities performed under § 721.1 as follows:

(1) Except as otherwise provided by applicable state insurance law, reimbursement or compensation is not limited with respect to insurance sales by the credit union or its employees which are directly related to an extension of credit by the credit union or directly related to the opening or maintenance of a share, share draft or share certificate account at the credit union;

(2) For insurance sales other than those described in paragraph (b)(1), a Federal credit union may receive an amount not exceeding the greater of the dollar amount or the cost amount;

(3) For group purchasing plans other than insurance, a Federal credit union may receive an amount not exceeding the cost amount.



(c) No official or employee of a Federal credit union or any immediate family member of an official or employee may receive any compensation or benefit, directly or indirectly, in conjunction with any activity under this regulation. For purposes of this section, "immediate family member" means a spouse, or a child, parent, grandchild, grandparent, brother or sister, or spouse of any such individual.

[FR Doc. 85-10110 Filed 4-25-85; 8:45 am]  
BILLING CODE 7535-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 85-ANE-13; Amdt. 39-5029]

#### Airworthiness Directives; Teledyne Continental Motors IO-470 and O-470 Series Engines

##### Correction

In FR Doc. 85-9241, beginning on page 15098 in the issue of Wednesday, April 17, 1985, make the following correction:

On page 15099, first column, in § 39.13, nineteenth line from the bottom of the page, "2138199" should have read "238199".

BILLING CODE 1505-01-M

#### 14 CFR Part 39

[Docket No. 85-NM-31-AD; Amdt. 39-5044]

#### Airworthiness Directives; Boeing Model 707 and 720 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

**SUMMARY:** This amendment adds a new airworthiness directive (AD) which requires inspection of the wing front spar upper chord of Boeing Model 707 and 720 airplanes. This action is promoted by a recent report of a 46-inch crack. The chords are subject to cracks, which if undetected will propagate to the point where fail-safe load cannot be supported.

**DATES:** Effective May 8, 1985.

Compliance schedule as prescribed in the body of the AD, unless already accomplished.

**ADDRESSES:** The service bulletin specified in this AD may be obtained upon request from the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. The service bulletin may also be

examined at FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or 9010 East Marginal Way South, Seattle, Washington.

**FOR FURTHER INFORMATION CONTACT:** Mr. Carlton Holmes, Airframe Branch, ANM-120S; (206) 431-2926. Mailing address: FAA, Northwest Mountain Region, Seattle Aircraft Certification Office, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

**SUPPLEMENTARY INFORMATION:** Recently one operator reported a 46-inch crack, which was located along the dry bay area between the inboard and outboard nacelles. When the crack extended into the fuel tank areas, fuel leakage resulted which led to discovery of the crack. Cracks of such length may lower the fail-safe load capability below required minimums and left undetected could result in a buckling of the upper front spar and failure to the wing.

Boeing Service Bulletin No. 3240, revised November 13, 1981, addresses cracking problems in the wing spar chords. Cracks in the front upper chord are attributed to a combination of corrosion and fatigue which results from slat actuator loads. The service bulletin recommended inspections at 1000 flight intervals, and provided repair information.

Since this situation is likely to exist or develop on other airplanes of the same type design, this AD requires inspection and repair, if necessary, in accordance with the Boeing service bulletin.

Further, since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

The FAA has determined that this regulation is an emergency regulation that is not major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the

person identified under the caption "FOR FURTHER INFORMATION CONTACT."

#### List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new airworthiness directive:

**Boeing:** Applies to Model 707 and 720 series airplanes certificated in all categories with 15,000 or more landings.

To insure continued structural integrity of the wing front spar upper chord, accomplish the following within 100 landings or 60 days, whichever occurs first, unless previously accomplished within the last 900 landings or 10 months:

A. Perform a close visual inspection of the wing front spar upper chord for cracks in accordance with Boeing Service Bulletin 3240, Revision 1, or later FAA approved revision. Repeat the inspection at intervals not to exceed 1,000 landings or one year, whichever occurs first.

B. If cracks or corrosion areas are found, repair prior to further flight in accordance with the above service bulletin or in a manner approved by the Manager, Seattle Aircraft Certification Office.

C. The temporary crack repairs described in the above service bulletin, Part III, Figure 2, may be performed; however, the crack must be reinspected at intervals not exceeding 300 landings and a permanent repair must be accomplished within 1,000 landings or one year, whichever occurs first after the temporary repair.

D. After each of the above inspections and repairs have been performed, apply BMS-3-23 or equivalent corrosion inhibitor to the affected areas.

E. Areas of wing front spar upper chord replaced or repaired in accordance with the repair kits specified in Boeing Service Bulletin 3240, are exempt from the inspections of paragraph A., above.

F. An alternate means of compliance which provides an acceptable level of safety may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

G. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. These documents may also be examined at FAA, Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective May 8, 1985.



(Secs. 313(a), 314(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 through 1430, and 1502); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89)

Issued in Seattle, Washington, on April 18, 1985.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 85-10138 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-13-M

#### 14 CFR Part 39

[Docket No. 85-ANE-13; Amdt. 39-5902]

#### Airworthiness Directives; Teledyne Continental Motors IO-470 and O-470 Series Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule, extension of compliance date.

**SUMMARY:** This amendment extends the date for compliance with the AD from April 15, 1985, the effective date of the AD, to April 30, 1985. The extension is needed to prevent unintended grounding of aircraft.

**EFFECTIVE DATE:** This action is effective April 26, 1985.

**FOR FURTHER INFORMATION CONTACT:** Robert R. Goodall, Aerospace Engineer, Propulsion Branch, ACE-140A, Atlanta Aircraft Certification Office, Federal Aviation Administration, 1075 Inner Loop Road, College Park, Georgia 30337, telephone (404) 763-7435.

**SUPPLEMENTARY INFORMATION:** On March 26, 1985, the FAA issued an AD applicable to certain Teledyne Continental Motors IO-470 engines and certain cylinder assemblies in inventory or installed on designated IO-470 series engines. The AD became effective on April 15, 1985. The AD was issued to prevent excessive valve stem wear, oil contamination, valve seizure, and total loss of engine power. The AD required compliance within 10 hours after the effective date of the AD. It was anticipated, at the time the AD was issued, that adequate notice would be provided to operators of the affected engines to avoid an immediate grounding of their aircraft. Due to unforeseen circumstances, however, it now appears that the compliance date of April 15, 1985 did not provide adequate notice to avoid immediate groundings. Therefore, this action amends the AD by changing the compliance date from "the effective date of the AD" (April 15, 1985) to April 30, 1985.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

#### Conclusion

This amendment merely extends the compliance date of an existing AD by fifteen days, to avoid unintended immediate grounding of aircraft. This is consistent with the intent of the original AD. No other change is being made to the original AD. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291, and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption "FOR FURTHER INFORMATION CONTACT."

#### List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (914 CFR 39.13) is amended by amending amendment 39-5029, Docket No. 85-ANE-13 as follows:

Under the adoption of the amendment section in the compliance line preceding the first paragraph (a) of the AD.

1. Delete the words "after the effective date of this AD, compliance is required as indicated unless already accomplished".

2. Insert, in lieu thereof, the words "after April 30, 1985 compliance is required as indicated unless already accomplished".

This amendment becomes effective on publication in the *Federal Register*.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.89)

Issued in Burlington, Massachusetts, on April 18, 1985.

Jack A. Sain,

Acting Director, New England Region.

[FR Doc. 85-10135 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-13-M

#### 14 CFR Part 71

[Airspace Docket No. 84-AWA-34]

#### Alteration of VOR Federal Airways

##### Correction

In FR Doc. 85-8594 beginning on page 14090 in the issue of Wednesday, April 10, 1985, make the following correction: On page 14091, in the first column, in the third line under "V-306", "Diasetta" should read "Daisetta".

BILLING CODE 1505-01-M

#### 14 CFR Part 71

[Airspace Docket No. 84-AWA-14]

#### Alteration of VOR Federal Airways

##### Correction

In FR Doc. 85-8592 beginning on page 14091 in the issue of Wednesday, April 10, 1985, make the following correction: On page 14092, in the first column, in the fifth line under "V-94", "Slat" should read "Salt".

BILLING CODE 1505-01-M

#### 14 CFR Part 75

[Airspace Docket No. 84-ANM-34]

#### Extension of Jet Route—Denver, CO

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment extends Jet Route J-157 from Denver, CO, to Keann Intersection to aid flight planning and improve the flow of air traffic at Denver, CO.

**EFFECTIVE DATE:** 0901 G.M.T., June 6, 1985.

**FOR FURTHER INFORMATION CONTACT:** Burton Chandler, Airspace and Air Traffic Rules Branch (ATO-230), Airspace—Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8783.

**SUPPLEMENTARY INFORMATION:**

#### History

On February 14, 1985, the FAA proposed to amend Part 75 of the Federal Aviation Regulations (14 CFR Part 785) to extend Jet Route J-157 from Denver, CO, to Keann Intersection to aid flight planning and improve the flow of air traffic at Denver, CO (50 FR 6198). Interested parties were invited to



participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6A dated January 2, 1985.

### The Rule

This amendment to Part 75 of the Federal Aviation Regulations amends a segment of Jet Route J-157 from Denver, CO, to Keann Intersection. This action will enhance IFR flight planning and the flow of air traffic in the affected area.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 75

Jet Routes, Aviation safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 75.100 of Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is amended, as follows:

#### 1-157-[Amended]

By removing the words "From the INT of Denver, CO, 058° and Gill, CO, 151° radials, via INT Denver 058° and substituting the words "From Denver, CO, via INT of Denver 058°"

[Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.89]

Issued in Washington, D.C., on April 19, 1985.

John Watterson,

Acting Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 85-10139 Filed 4-25-85; 8:45 am]

BELLING CODE 4910-13-M

### 14 CFR Part 97

[Docket No. 24598; Amdt. No. 1293]

### Standard Instrument Approach Procedures; Miscellaneous Amendments

**AGENCY:** Federal Aviation Administration (FAA) DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**EFFECTIVE DATE:** An effective date for each SIAP is specified in the amendatory provisions.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

#### For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Field Office which originated the SIAP.

#### For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-430), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

#### By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

#### FOR FURTHER INFORMATION CONTACT:

Donald K. Funai, Flight Procedures Standards Branch (AFO-230), Air Transportation Division, Office of Flight Operations, Federal Aviation Administration, 800 Independence

Avenue, SW., Washington, D.C. 20591; telephone (202) 426-8277.

**SUPPLEMENTARY INFORMATION:** This amendment of Part 97 of the Federal Aviation Regulations (14 CFR Part 97) prescribes new, amended, suspended, or revoked Standard Instrument

Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 14 CFR Part 51, and § 97.20 of the Federal Aviation Regulations (FARs). The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, and 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to Part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPs criteria were applied to the conditions existing or anticipated at the affected airports. Because of the



close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

#### List of Subjects in 14 CFR Part 97

Approaches, Standard instrument, Aviation safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 97 of the Federal Aviation Regulations (14 CFR Part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, Effective at 0901 G.m.t. on the dates specified, as follows:

1. By Amending § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN SIAPs identified as follows:

Effective June 6, 1985

- Kenai, AK—Kenai Muni, VOR RWY 19, Amdt. 13  
 Selawik, AK—Selawik, VOR RWY 27, Orig.  
 Selawik, AK—Selawik, VOR/DME RWY 9, Orig.  
 Selawik, AK—Selawik, VOR RWY 9, Orig.  
 Dumas, AR—Billy Free Municipal, VOR/DME RWY 36, Orig.  
 Fayetteville, AR—Drake Field, VOR-A, Amdt. 23  
 Rogers, AR—Rogers Muni Airport-Carter Field, VOR RWY 1, Amdt. 9  
 Rogers, AR—Rogers Muni Airport-Carter Field, VOR/DME RWY 19, Amdt. 7  
 Hayden, CO—Yampa Valley, VOR-A, Amdt. 1  
 Pensacola, FL—Pensacola Regional, VOR RWY 7, Amdt. 2  
 Boise, ID—Boise Air Terminal (Gowen Field), VOR RWY 10R, Amdt. 19  
 Boise, ID—Boise Air Terminal (Gowen Field), VOR/DME RWY 10R, Amdt. 5  
 Cambridge, MD—Cambridge-Dorchester, VOR-A, Amdt. 4  
 Leonardtown, MD—St. Mary's County, VOR RWY 11, Amdt. 1  
 Leonardtown, MD—St. Mary's County, VOR RWY 29, Amdt. 2  
 Baytown, TX—RWJ Airpark, VOR/DME RWY 33, Orig.  
 Baytown, TX—RWJ Airpark, VOR-A, Amdt. 1  
 Ennis, TX—Ennis Muni, VOR/DME-A, Orig.  
 Appleton, WI—Outagamie County, VOR/DME RWY 3, Amdt. 2

2. By amending § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, and SDF/DME SIAPs identified as follows:

Effective June 6, 1985

- Fayetteville, AR—Drake Field, LOC RWY 16, Amdt. 13  
 Harrison, AR—Boone County, LOC RWY 36, Amdt. 4  
 Pensacola, FL—Pensacola Regional, LOC BC RWY 34, Amdt. 10

Hoquiam, WA—Bowerman, LOC RWY 24, Amdt. 2

Appleton, WI—Outagamie County, LOC BC RWY 21, Amdt. 3

Effective May 9, 1985

Huntsville, AL—Huntsville-Madison Co Apt—Carl T. Jones Fld, LOC RWY 18L, Orig.

3. By amending § 97.27 NDB and NDB/DME SIAPs identified as follows:

Effective June 6, 1985

- Gambell, AK—Gambell, NDB-A Amdt. 1  
 Gambell, AK—Gambell, NDB-B Amdt. 1  
 Gambell, AK—Gambell, NDB/DME RWY 16, Orig.  
 Gambell, AK—Gambell, NDB/DME RWY 34, Orig.  
 Rogers, AR—Rogers Muni Airport-Carter Field, NDB RWY 19, Amdt. 2  
 Santa Ynez, CA—Santa Ynez, NDB RWY 8, Orig.  
 Pensacola, FL—Pensacola Regional, NDB RWY 34, Amdt. 15  
 Winston-Salem, NC—Smith Reynolds, NDB RWY 33, Amdt. 21  
 Burnet, TX—Burnet Muni/Kate Craddock Field, NDB RWY 1, Amdt. 1  
 Appleton, WI—Outagamie County, NDB RWY 3, Amdt. 9  
 Appleton, WI—Outagamie County, NDB RWY 11, Amdt. 2  
 Appleton, WI—Outagamie County, NDB RWY 29, Amdt. 2

Effective April 16, 1985

Hickory, NC—Hickory Muni, NDB, RWY 24, Amdt. 3

Effective April 12, 1985

Gastonia, NC—Gastonia Muni, NDB RWY 3, Amdt. 4

4. By amending § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME and MLS/RNAV SIAPs identified as follows:

Effective June 6, 1985

- Barrow, AK—Wiley Post-Will Rogers Memorial, ILS/DME RWY 6, Amdt. 2  
 Kenai, AK—Kenai Muni, ILS RWY 19, Amdt. 4  
 Prescott, AZ—Ernest A. Love Field, ILS/DME RWY 21, Orig.  
 Hot Springs, AR—Memorial Field, ILS RWY 5, Amdt. 10  
 Pensacola, FL—Pensacola Regional, ILS RWY 16, Amdt. 12  
 Winston-Salem, NC—Smith Reynolds, ILS RWY 33, Amdt. 22  
 Westhampton Beach, NY—Suffolk County, ILS RWY 24, Amdt. 8  
 North Myrtle Beach, SC—Grand Strand, ILS RWY 23, Amdt. 6  
 Appleton, WI—Outagamie County, ILS RWY 3, Amdt. 11

Effective April 16, 1985

Hickory, NC—Hickory Muni, ILS RWY 24, Amdt. 5

5. By amending § 97.31 RADAR SIAPs identified as follows:

Effective June 6, 1985

Columbia, SC—Owens Field, RADAR-1, Orig.

6. By amending § 97.33 RNAV SIAPs identified as follows:

Effective June 6, 1985

Burnet, TX—Burnet Muni/Kate Craddock Field, RNAV RWY 19, Amdt. 1

Houston, TX—Hull Field, RNAV RWY 17, Amdt. 4

Houston, TX—Hull Field, RNAV RWY 35, Amdt. 5

Appleton, WI—Outagamie County, RNAV RWY 29, Amdt. 2

Effective April 12, 1985

Gastonia, NC—Gastonia Muni, RNAV RWY 3, Amdt. 2

(Secs. 307, 313(a), 601, and 1110, Federal Aviation Act of 1958 (49 U.S.C. 1348, 1354(a), 1421, and 1510); 49 U.S.C. 106(g) [Revised, Pub. L. 97-449, January 12, 1983]; and 14 CFR 11.49(b)(3)).

**Note.**—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Note.**—The incorporation by reference in the preceding document was approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

Issued in Washington, D.C. on April 19, 1985.

John S. Kern,

Acting Director of Flight Operations.

[FR Doc. 85-10136 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### 15 CFR Parts 379 and 399

[Docket No. 50465-5065]

#### Amendments To Export Controls on Software and Electronic Computers

**AGENCY:** Office of Export Administration, International Trade Administration, Commerce.

**ACTION:** Final rule.

**SUMMARY:** This rule delegates ECCN 1566A of the Commodity Control List covering software (15 CFR 399.1) and adds software formerly described in ECCN 1566A to 15 CFR 379.4, thus removing the validated licensing requirements for the export of certain software to destinations in Country Groups T and V [except the People's



Republic of China and Afghanistan). This rule revises General License GTDR to authorize exports of certain software, except to Country Groups S and Z. This rule also amends ECCN 1565A of the Commodity Control List to clarify the scope of controls on "embedded" computers and certain computer peripherals, and to make clear that in calculating Processing Data Rate (PDR) to determine eligibility of systems under the first 1565 entry in Supplement No. 1 to Part 373, exporters of computers under Distribution License should use the "floating point" PDR.

**EFFECTIVE DATE:** April 30, 1985.

**FOR FURTHER INFORMATION CONTACT:** For software questions, call Raj Dheer on (202) 377-2290, and for questions on ECCN 1565A contact Randy Williams on (202) 377-3109, Scientific & Electronic Equipment Division, Office of Export Administration, Department of Commerce, Washington, D.C. 20230.

#### SUPPLEMENTARY INFORMATION

#### Regulatory Changes

On December 31, 1984, the Office of Export Administration issued a rule (49 FR 50608-50632) revising export controls on certain computer equipment, software, and communication switching equipment. The effective date of any new controls imposed by that rule was deferred until April 29, 1985.

Supplement No. 1 to § 399.1 (the Commodity Control List) includes all commodities subject to Department of Commerce export control. This rule deletes ECCN 1566A of the Commodity Control List covering software and adds software formerly described in ECCN 1566A to § 379.4. A major result of this change is to remove validated license requirements for the export of certain software to destinations in Country Groups T and V (except the People's Republic of China and Afghanistan).

General license GTDR is revised to authorize exports of certain software, except to Country Groups S and Z.

This rule also amends ECCN 1565A of the Commodity Control List to clarify the scope of controls on "embedded" computers and certain computer peripherals. In addition, exporters of computers under the Distribution License are advised that in calculating Processing Data Rate (PDR) to determine eligibility of systems under the first 1565 entry in Supplement No. 1 to Part 373, they should use the "floating point" PDR.

Finally, this rule further extends the "Saving Clause" contained in 50 FR 4503 (January 31, 1985) from April 29, 1985 to May 29, 1985 for those items not covered by this rule. This will permit certain

items removed from general license authorization by the December 31, 1984 revisions (49 FR 50608) and not covered by this rule to continue to be shipped under general license up to May 29, 1985.

The effective date of the amendments made herein is April 30, 1985.

#### Rulemaking Requirements

In connection with various rulemaking requirements, the Office of Export Administration has determined that:

1. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, an opportunity for public participation, and a delay in effective date (5 U.S.C. 553) are inapplicable because this regulation involves a foreign affairs function of the United States.

2. This rule reduces the regulatory burden on exporters because it removes validated license requirements (approved under OMB Control No. 0625-0001) for the export of certain software to most destinations. The written assurance requirement is covered under OMB Control No. 0625-0140.

3. Because a notice of proposed rulemaking is not required, this rule is not a rule within the meaning of section 601(2) of the Regulatory Flexibility Act, 5 U.S.C. 601(2) and is not subject to the requirements of that Act. Accordingly, no initial or final Regulatory Flexibility Analysis has been or will be prepared.

4. This rule is not a rule or regulation within the meaning of Section 1(a) of Executive Order 12291 and, accordingly, is not subject to the requirements of that Order. Accordingly, no preliminary or final Regulatory Impact Analysis has been or will be prepared.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

#### List of Subjects in 15 CFR Part 379 and 399

Exports, Science and Technology.

Accordingly, the Export Administration Regulations (15 CFR Parts 368-399) are amended as follows:

#### PART 379—[AMENDED]

##### § 379.1 [Amended]

1. Section 379.1 is amended by adding a final sentence to paragraph (a), reading "All software is technical data."

§ 2. Section 379.4 is amended by adding a paragraph (b)(3) following the Note in (b)(2), reading as follows:

##### § 379.4 General license GTDR; Technical data under restriction.

(b) \* \* \*

(3) Software, *unless* it is explicitly listed in Supplement No. 3 to Part 379 or in any entry on the Commodity Control List (e.g. ECCN's 1091A, 1354A, 1355A, 1527A, 1532A, 1567A) or applications software identified in section 379.4(c) and (d).

3. Section 379.4(f)(1) is amended by adding paragraph (i)(a), which is currently reserved, as follows:

##### § 379.4 General license GTDR; Technical data under restriction.

(f) \* \* \*

(i) \* \* \*

(i) \* \* \*

(a) Electronic computers, if the technical data is software listed in Supplement No. 3 to Part 379. Software not listed in Supplement No. 3 to Part 379 or any ECCN entry, or in § 379.4 (c) or (d) may be exported to Country Groups T & V, without written assurance.

4. Section 379.4(g) is amended by revising paragraph (g)(2), as follows:

##### § 379.4 General license GTDR; technical data under restriction.

(g) \* \* \*

(2) No software or technical data may be exported or reexported under General License GTDR when such software or technical data are listed on the Commodity Control List (Supplement No. 1 to § 399.1). See ECCNs 1091A, 1354A, 1355A, 1527A, 1532A, and 1567A. In addition, exports of application software included in § 379.4 (c) and (d) require a validated license. See § 379.4(f)(1)(i)(a) for written assurance requirements applicable to software.

5. Section 379.4(i) is revised to read as follows:

(i) *Additional restrictions applicable to the People's Republic of China.* In addition to the prohibitions of § 379.4 (c) and (d), no technical data related to commodities identified on the Commodity Control List (Supplement No. 1 to § 399.1) as controlled for reasons of national security, nuclear non-proliferation, or crime control may be exported to the People's Republic of China under General License GTDR. In addition, software covered by Supplement 3 to Part 379 requires a



validated license for export to the PRC. These prohibitions do not apply, however, to technical data described in § 379.4(b).

6. A new Supplement No. 3 to Part 379 is added to read as follows:

#### Supplement No. 3.—Computer Software

Software described in this Supplement is subject to the written assurance requirements of § 379.4(f)(1)(i)(a) and requires an individual validated license for export to Country Groups QSWYZ, the People's Republic of China, and Afghanistan.

#### Technical Notes

1. "Software" is defined as follows:

"Software"—A collection of one or more "programs" or "microprograms" fixed in any tangible medium of expression.

"Program"—A sequence of instructions to carry out a process in, or convertible into, a form executable by an electronic computer.

"Microprogram"—A sequence of elementary instructions, maintained in a special storage, the execution of which is initiated by the introduction of its reference instruction into an instruction register.

2. "Software" is categorized as follows (there is a close relationship and possible overlap among these categories):

"Development system"—"Software" to develop or produce "software". This includes "software" to manage those activities. Examples of a "development system" are programming support environments, software development environments, and programmer productivity aids.

"Software" to convert a convenient expression of one or more processes ("source code" or "source language") into equipment executable form ("object code" or "object language").

"Diagnostic system"—

"Software" to isolate or direct "software" or equipment malfunctions.

"Maintenance system"—

"Software" to:

(a) Modify "software" or its associated documentation in order to correct faults, or for other updating purposes; or

(b) "Maintain" equipment;

"Operating system"—

"Software" to control:

(a) The operation of a "digital computer" or of "related equipment"; or

(b) The loading or execution of "programs".

"Application software"—

"Software" not falling within any of the definitions of the other categories of "software".

3. "Specially designed software" is defined as:

The minimum "operating systems", "diagnostic systems", "maintenance systems" and "application software" necessary to be executed on a particular equipment to perform the function for which it was designed. To make other incompatible equipment perform the same function requires:

(a) Modification of this "software"; or

(b) Addition of "programs".

(For a complete list of definitions of terms used in this Supplement, see Advisory Note

12 below; see also ECCN 1565 for additional definitions relating to electronic computers.)

List of Software Subject To This Supplement to Part 379:

(a) "Software" of whatever category, as follows:

(i) "Software" designed or modified for any computer that is part of a computer series designed and produced within Country Groups Q, W, Y, or Z, the People's Republic of China, or Afghanistan;

except "application software" designed for and limited to:

(i) Accounting, general ledger, inventory control, payroll, accounts receivable, personnel records, wages calculation on invoice control;

(ii) Data and text manipulation such as sort/merge, text editing, data entry or work processing;

(iii) Data retrieval from established data files for purposes of report generation or inquiry for the functions described in (i) or (ii) above; or

(iv) The non "real time processing" of pollution sensor data at fixed sites or in civil vehicles for civil environmental monitoring purposes;

(2) "Software" designed or modified for the design, development or production of items controlled by ECCNs on the Commodity Control List identified by the code letter "A", by the International Traffic in Arms Regulations, by 10 CFR Part 110 or by 10 CFR Part 810;

(3) "Software" designed or modified for:

(i) Controlled "hybrid computers";

(ii) One or more of the functions described in ECCN 1565(h)(1)(i) (A) to (M) or for "digital computers" or "related equipment" designed or modified for such functions, except the minimum "specially designed software" in machine executable form for "digital computers" and "related equipment" thereby freed from control only by ECCN 1565(h)(2)(i) or (iii), and only when supplied with the equipment or systems;

(4) "Software" for computer-aided design, manufacture, inspection or test of items controlled by ECCNs on the Commodity Control List identified by the code letter "A", by the International Traffic in Arms Regulations, by 10 CFR Part 110 or by 10 CFR Part 810;

(5) "Software" designed or modified to provide certifiable multi-level security or certifiable user isolation applicable to government classified material or to applications requiring an equivalent level of security, or "software" to certify such "software";

(b) Categorized "software", as follows:

(1) "Development systems";

(i) "High-level language" "development systems" designed for or containing "programs" or "databases" special to the development or production of:

(A) "Specially designed software" controlled by ECCNs on the Commodity Control List identified by the code letter "A", by the International Traffic in Arms

Regulations, by 10 CFR Part 110 or by 10 CFR Part 810;

(B) "Software" controlled by sub-paragraphs (a)(2), (a)(3), (b)(5)(v), or (b)(5)(vi) of this Supplement, including any subset designed or modified for use as part of such a "development system";

(ii) "High-level language" "development systems" designed for, or containing the "software" tools and "databases" for, the development or production of "software", or any subset designed or modified for use as part of a "development system" such as or equivalent to:

(A) Ada Programming Support Environment (APSE);

(B) Any subset of APSE, as follows:

(1) Kernel APSE;

(2) Minimal APSE;

(3) Ada compilers specially designed as an integrated subset of APSE; or

(4) Any other subset of APSE;

(C) Any superset of APSE; or

(D) Any derivative of APSE;

(2) "Programming systems";

(i) "Cross-hosted" compilers and "cross-hosted" assemblers;

(ii) Compilers or interpreters designed or modified for use as part of a "development system" controlled by sub-paragraph (b)(1) above;

(iii) Disassemblers, decompilers or other "software" that convert "programs" in object or assembly language into a higher level language, except simple debugging "application software", such as mapping, tracing, checkpoint/restart, breakpoint, dumping and the display of the storage contents or their assembly language equivalent;

(3) "Diagnostic systems" or "maintenance systems" designed or modified for use as part of a "development system" controlled by sub-paragraph (b)(1) above;

(4) "Operating systems";

(i) "Operating systems" designed or modified for "digital computers" or "related equipment" exceeding any of the following limits:

(A) Central processing unit—"main storage" combinations:

(1) "Total processing data rate"—48 million bit per second;

(2) "Total connected capacity" of "main storage"—25.2 million bit;

(3) "Virtual storage" capability—512 M Byte;

(B) Input-output control unit—drum, disk or cartridge-type streamer tape drive combinations:

(1) "Total transfer rate"—15 million bit per second;

(2) "Total access rate"—320 access per second;

(3) Total connected "net capacity"—7,000 million bit;

(4) "Maximum bit transfer rate" of any drum or disk drive—10.3 million bit per second;

(C) Input/output control unit—bubble memory combinations: Total connected "net capacity"—2.1 million bit;

(D) Input-output control unit—magnetic tape drive combinations:

<sup>1</sup> Department of Defense certifiable under section (b)(3) of "Department of Defense Trusted Computer System Evaluation Criteria", published in DOD Computer Security Center, Fort Meade, MD 20755.



- (1) "Total transfer rate"—5.2 million bit per second;
- (2) Number of magnetic tape drives—twelve;
- (3) "Maximum bit transfer rate" of any magnetic tape drive—2.6 million bit per second;
- (4) "Maximum bit packing density"—63 bit per mm. (1,600 bit per inch) per track;
- (5) Maximum tape read/write speed—508 cm. (200 inch) per second;

Note.—This sub-paragraph does not control "operating systems" designed or modified for "digital computers" or "related equipment".

- (a) Not exceeding the above limits even when the "operating systems" can also be used on "digital computers" or "related equipment" exceeding the above limits; or
- (b) Belonging to a series containing models exceeding the above limits, if the "operating systems" are used on "digital computers" or "related equipment" of the series that do not exceed the above limits.
- (ii) "Operating systems" providing online transaction data processing that permit integrated teleprocessing and "on-line updating" of "databases";
- (5) "Application software";
- (i) "Software" for cryptologic or cryptanalytic applications;
- (ii) Artificial intelligence "software", including "software" normally classified as expert systems, that enables a "digital computer" to perform functions normally associated with human perception and reasoning or learning;
- (iii) "Database management systems" designed to handle "distributed databases" for

- (A) Fault tolerance by using techniques such as maintenance of duplicated "databases"; or
- (B) Integrating data at a single site from independent remote "databases";
- (iv) "Software" designed to adapt "software" resident on one "digital computer" for use on another "digital computer", except "software" to adapt between two legally exported machines.

#### Advisory Notes

- Advisory Note 1: *Reserved*.  
 Advisory Note 2: *Reserved*.  
 Advisory Note 3: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "software" initially exported to those destinations before January 1, 1984, provided that:
- (a) The "software" is identical to and in the same language form (source or object) as initially exported, allowing minor updates for the correction of errors that do not modify the initially exported functions;
  - (b) The accompanying documentation does not exceed the level of the initial export;
  - (c) The "software" is exported to the same controlled destination as the initial export.
- Advisory Note 4: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "application software" controlled by sub-paragraph (a)(1) above, but not otherwise

listed in this Supplement or ECCNs on the Commodity Control List identified by the code letter "A", provided that:

- (a) The "application software" is designed for and limited to the following:
- (1) The approved end-use of legally exported equipment or systems in conjunction with any computer that is part of a computer series produced within a controlled area and based on a design originating in a COCOM country; or

(2) The monitoring and control of industrial processes limited to the production of items not described by ECCNs on the Commodity Control List identified by the code letter "A", by the International Traffic in Arms Regulations, by 10 CFR Part 110 or by 10 CFR Part 810; and

- (b) No restricted technical data is provided.
- Advisory Note 5: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "software" not exceeding 5,000 statements in "source language", excluding data, provided that:

(a) The "software" is neither designed nor modified for use as a module of a larger "software" module or system that in total exceeds this limit;

(b) The "software" is not controlled by sub-paragraph (b)(5) above; and

(c) The Office of Export Administration is reasonably satisfied that:

(1) The "software" will be used primarily for the specific non-strategic application for which the export would be approved;

(2) The type and characteristics of such "software" are reasonable for this application; and

(3) The "software" will not be used for the design, development or production of items controlled by ECCNs on the Commodity Control List identified by the code letter "A", by the International Traffic in Arms Regulations, by 10 CFR Part 110 or by 10 CFR Part 810.

Advisory Note 6: *Reserved*.

Advisory Note 7: *Reserved*.

Advisory Note 8: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of normal commercial "software" for civil Air Traffic Control (ATC) systems approved for export, provided that:

(a) The "software" is commonly used by civil Air Traffic Control authorities outside controlled areas, but not precluding the personalization of certain parameters for civil Air Traffic Control authorities wherever located;

(b) The "software" is not designed or modified for any "digital computer" that is part of a "digital computer" series designed and produced within a controlled area;

(c) The "software" is the minimum necessary to accomplish the normal civil Air Traffic Control functions outside controlled areas;

(d) The "software" will not contain or be capable of accomplishing any of the following functions:

- (1) Electronic Counter Counter Measures (ECCM);
- (2) Weapon display, allocation or operation;

(3) Intercept guiding capability; or

(4) Interfacing with altitude determining radars, except secondary search radars;

(e) The "software" is further limited by the amount of "source code", which is to be the minimum necessary for the use (i.e., installation, operation and maintenance) of the "software";

(f) In addition to the above limitations, the only other system "software" allowed is the minimum "programming system" for the maintenance of the "software".

(g) A signed statement of the end-user or importing agency containing a full description of the "software" and its characteristics vis-a-vis the sub-paragraphs above, its intended application and workload and a complete identification of all end-users and their activities is provided;

(h) The "software" will not be used to provide or process data associated with military control centers or military radars or otherwise be associated with such radars or centers; and

(i) The type and characteristics of the "software" are reasonable for the specific civil Air Traffic Control applications.

Advisory Note 9: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "operating systems" controlled only by sub-paragraph (b)(4)(ii) above when supplied with "digital computers" and "related equipment" exported under the provision of ECCN 1565, Advisory Notes 9 and 12, provided that these "operating systems" are:

- (a) For use with a "digital computer" exported under the provisions of ECCN 1565;
- (b) In machine executable version;
- (c) Limited to the minimum "standard commercially available" "software"; and
- (d) Not designed or modified for "database management systems" controlled by sub-paragraph (b)(5)(iii) above.

Advisory Note 10: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "software" controlled by sub-paragraph (a)(3)(ii) above for "digital computers" and "related equipment" exported under the provisions of ECCN 1529, Advisory Note 5, or ECCN 1565, Advisory Notes 5 and 9, provided that:

(a) The "software" is limited to:

(1) The minimum necessary for the approved application;

(2) Machine executable form; and

(3) "Specially designed software" for

(i) Equipment likely to be approved for export solely under ECCN 1529, Advisory Note 5;

(ii) Equipment likely to be approved for export under ECCN 1565, Advisory Note 5, for one or more of the functions described in ECCN 1565(h)(1)(i)(A), (B) or (D);

(iii) Equipment likely to be approved for export under ECCN 1565, Advisory Note 9, for one or more of the functions described in ECCN 1565(h)(1)(i)(A), (B), or (C);

(b) The "specially designed software" for "signal processing" and "image enhancement" does not provide for more than one of the following:



- (1) Time compression; or  
 (2) Transformations between domains (e.g. Fast Fourier Transform or Walsh Transform).

Advisory Note 11: Licenses are likely to be approved for export to satisfactory end-users in Country Groups QWY, the People's Republic of China (PRC) and Afghanistan of "software" controlled by sub-paragraph (a)(3)(ii) above for "digital computers" and "related equipment" exported under the provisions of ECCN 1565, Advisory Note 12, provided that the "software" is limited to:

- (a) "Software" for one or more of the functions described in ECCN 1565(h)(1)(i)(A), (B), or (C);  
 (b) The minimum necessary for the approved applications; and  
 (c) Machine executable form.

Advisory Note 12: Definitions of Terms Used in this Supplement:

"Analog computer"—Equipment that can, in the form of one or more continuous variables:

- (a) Accept data;  
 (b) Process data; and  
 (c) Provide output of data.

"Application software"—"Software" not falling within any of the definitions of the other categories of "software".

"Cross-hosted"—For "programming systems", those that produce "programs" for a model of electronic computer different from that used to run the "programming system", i.e., they have code generators for equipment different from the host computer.

"Database"—A collection of data, defined for one or more particular applications, physically located and maintained in one or more electronic computers or "related equipment".

"Database management system"—"Applications software" to manage and maintain a "database" in one or more prescribed logical structures for use by other "application software" independent of the specific methods used to store or retrieve the "database".

"Development system"—"Software" to develop or produce "software". This includes "software" to manage those activities. Examples of a "development system" are programming support environments, software development environments, and programmer productivity aids.

"Diagnostic system"—"Software" to isolate or detect "software" or equipment malfunctions.

"Digital computer"—Equipment that can, in the form of one or more discrete variables:

- (a) Accept data;  
 (b) Store data or instructions in fixed or alterable (writable) storage devices;  
 (c) Process data by means of a stored sequence of instructions that is modifiable; and  
 (d) Provide output of data.

Note.—Modifications of a stored sequence of instructions include replacement of fixed storage devices, but not a physical change in wiring or interconnections.

"Distributed database"—A "database" physically located and maintained in part or

as a whole in two or more interconnected electronic computers or "related equipment", such that inquiries from one location can involve "database" access in other interconnected electronic computers or "related equipment".

"Firmware"—see "microprogram".

"High-level language"—A programming language that does not reflect the structure of any one given electronic computer or that of any one given class of electronic computers.

"Hybrid computer"—Equipment that can:  
 (a) Access data;  
 (b) Process data, in both analog and digital representations; and  
 (c) Provide output of data.

"Maintenance system"—"Software" to:

- (a) Modify "software" or its associated documentation in order to correct faults, or for other updating purposes; or  
 (b) Maintain equipment.

"Microprogram"—A sequence of elementary instructions, maintained in a special storage, the execution of which is initiated by the introduction of its reference instruction into an instruction register.

"Object code" or "object language"—See "programming system".

"On-line updating"—Processing in which the contents of a "database" can be amended within a period of time useful to interact with an external request.

"Operating system"—"Software" to control:

- (a) The operation of a "digital computer" or of "related equipment"; or  
 (b) The loading or execution of "programs".

"Program"—A sequence of instructions to carry out a process in, or convertible into, a form executable by an electronic computer.

"Programming system"—"Software" to convert a convenient expression of one or more processes ("source code" or "source language") into equipment executable form ("object code" or "object language").

"Related equipment"—Equipment 'embedded' in, 'incorporated' in, or 'associated' with electronic computers, as follows:

- (a) Equipment for interconnecting "analog computers" with "digital computers";  
 (b) Equipment for interconnecting "digital computers";  
 (c) Equipment interfacing electronic computers to "local area networks" or to "wide area networks";  
 (d) Communication control units;  
 (e) Other input/output (I/O) control units;  
 (f) Recording or reproducing equipment referred to ECCN 1565 by ECCN 1572;  
 (g) Displays; or  
 (h) Other peripheral equipment.

Note.—"Related equipment" containing an "embedded" or "incorporated" electronic computer, but lacking "user accessible programmability", does not thereby fall within the definition of an electronic computer.

"Self-hosted"—For "programming systems", those producing "programs" for the same model of electronic computer as that used to run the "programming system", i.e., they only have code generators for the host computer.

"Software"—A collection of one or more "programs" or "microprograms" fixed in any tangible medium of expression.

"Source code" or "source language"—See "programming system".

"Specially designed software"—The minimum "operating systems", "diagnostic systems", "maintenance systems" and "application software" necessary to be executed on a particular equipment to perform the function for which it was designed. To make other incompatible equipment perform the same function requires:

- (a) Modification of this "software" or  
 (b) Addition of "programs".

"Standard commercially available"—For "Software" that is

- (a) Commonly supplied to general purchasers or users of equipment outside controlled areas, but not precluding the personalization of certain parameters for individual customers wherever located;  
 (b) Designed and produced for civil applications;

(c) Not designed or modified for any "digital computer" that is part of a "digital computer" series designed and produced within a controlled area; and

- (d) Supplied in a commonly distributed form.

Technical Note.—In the case of "software" for mainframe "digital computers" that may have a "virtual storage capability" exceeding the limit of sub-paragraph (b)(4)(i)(A)(3) and that may be considered for export under the conditions of ECCN 1565, Advisory Notes 9 & 12, the limitation of the "virtual storage capability" of 512 MByte does not apply.

Advisory Note 13: Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China (PRC) of software that has been approved previously for export and standard commercial packages for business applications, for example:

- (1) Operating systems for transaction processing and real time updating, and  
 (2) Relational database management systems.

## PART 399—[AMENDED]

7. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1565A is amended by adding a Note following paragraph (h)(2)(i) of the List of Electronic Computers and Related Equipment Controlled by ECCN 1565A, and adding a Note following (h)(2)(vi) as follows:

1565A Electronic computers, "related equipment", \* \* \*

- (h) \* \* \*  
 (2) Except: \* \* \*  
 (i) \* \* \*

Note.—Equipment or systems are released from control under subparagraph (i) only if the "digital computer" portion of the equipment or system meets the following requirements:

- (a) The circuit board(s) that contain the "digital computer" are company



specific products whose design intermixes on the same board the digital computer with other circuit components that are essential to the operation of the equipment or system;

(b) The circuit board(s) that contain the "digital computer" are not available as independent, general purpose, OEM products except as service spare parts; and

(c) The "digital computer" is not the principal component of the equipment. Equipment or systems containing general purpose "digital computer" circuit boards such as the LSI-11 and the SBC/80 are not released from control by subparagraph (i).

(vi) \*\*\*

**Note.**—Subparagraphs (v) and (vi) above release from control identified peripherals only if the following conditions are met:

(a) Microprocessor microcircuits contained in the peripheral are essential and dedicated solely to the operation of the peripheral equipment; and  
—Are not the principal element of the peripheral equipment; and  
—Do not exceed a total processing date rate of 28 Megabit per second.

(b) The peripheral equipment is designed to permit only loading or inserting "programs" that do not change that basic characteristics of the peripheral equipment and do not raise performance parameters above the levels specified for release; and

(c) The user is not provided with technical data or software to change the sequence of instructions comprising the loaded or inserted program.

8. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1566A is removed.

The Saving Clause in the preamble to the document appearing at 49 FR 50608, on page 50609, December 31, 1984, as amended at 50 FR 4503, is revised to read as follows:

#### **Saving Clause**

Items which were removed from general license authorizations as a result of this rule (49 FR 50608, Dec. 31, 1984) may be exported under the previous general license provisions up to and including May 29, 1985 except for those items covered by the rule of (date of publication) for which the effective date is April 30, 1985. Any items subject to this Saving Clause not actually exported before midnight May 29, 1985 require a validated export license.

Authority: Secs. 203, 206, Pub. L. 95-223, Title II, 91 Stat. 1628, 1629 (50 U.S.C. 1702, 1704), Executive Order No. 12470 of March 30,

1984 (49 FR 13099, April 3, 1984), Presidential Notice of March 28, 1985 (50 FR 12513, March 29, 1985).

Dated: April 24, 1985.

John K. Boidock,

Director, Office of Export Administration,  
International Trade Administration.

[FR Doc. 85-10288 Filed 4-24-85; 2:28 pm]

BILLING CODE 3510-DT-M

## **DEPARTMENT OF LABOR**

### **Employment and Training Administration**

#### **20 CFR Part 629**

### **Job Training Partnership Act (JTPA); Single Unit Charge Agreements Involving Training of Youths**

**AGENCY:** Employment and Training  
Administration, Labor.

**ACTION:** Final rule.

**SUMMARY:** The Department of Labor is conforming the Job Training Partnership Act regulations to the requirements of the Carl D. Perkins Vocational Education Act relating to single unit charge agreements involving training of youths, to broaden the number of categories of training results which exempt such costs from allocation or proration among several cost categories.

**EFFECTIVE DATE:** April 26, 1985.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert N. Colombo, Director, Office of Employment and Training Programs, Employment and Training Administration, U.S. Department of Labor, Room 6402, 601 D Street, NW., Washington, D.C. 20213. Telephone: 202-376-6093.

**SUPPLEMENTARY INFORMATION:** Pursuant to JTPA, the Department of Labor (DOL) enters into agreements with State Governors to operate programs to prepare youth and unskilled adults for entry into the labor force and to afford job training to those economically disadvantaged individuals and other individuals facing serious barriers to employment, who are in special need of such training to obtain productive employment. JTPA section 2, 29 U.S.C. 1501. As part of the general program requirements of JTPA, "[c]ommercially available training packages, including advanced learning technology, may be purchased for off-the-shelf prices and without requiring a breakdown of the cost components of the package if such packages are purchased competitively and include performance criteria." JTPA section 141(d)(3), 29 U.S.C. 1551(d)(3).

Section 108 of JTPA, however, limits certain costs under the Act. 29 U.S.C.

1516. As a result, § 629.38(e) of the JTPA regulations provides that in assigning costs to the training category, the Governor shall ensure that:

(2) Costs which are billed as a single unit charge do not have to be allocated or prorated among the several cost categories but may be charged entirely to training when the agreement:

(i) Is for training;  
(ii) Is fixed unit price; and  
(iii) Stipulates that full payment for the full unit price will be made only upon completion of training by a participant and placement of the participant into unsubsidized employment in the occupation trained for and at not less than the wage specified in the agreement.

On October 19, 1984, subsequent to the promulgation of the above regulation, section 7 of Pub. L. 98-524, the Carl D. Perkins Vocational Education Act (98 Stat. 2435, 2491), was enacted, providing that:

Sec. 7. Notwithstanding section 629.38(e)(2)(iii) of title 20 of the Code of Federal Regulations, relating to allowable training costs under the Job Training Partnership Act, payment for training packages purchased competitively pursuant to section 141(d)(3) of such Act in the case of youth shall include payment for the full unit price if the training results in either placement in unsubsidized employment or the attainment of the outcome specified in section 106(b)(2) of such Act.

The JTPA section 106(b)(2) outcomes mentioned above are "(A) attainment of recognized employment competencies recognized by the private industry council, (B) elementary, secondary, and postsecondary school completion, or the equivalent thereof, and (C) enrollment in other training programs or apprenticeships, or enlistment in the Armed Forces." 29 U.S.C. 1516(B)(2).

The enactment of section 7 of Pub. L. 98-524 supersedes the provisions of 20 CFR 629.38(e)(2)(iii). Therefore, for information and completeness, DOL has determined to amend the JTPA regulation to conform to the statute.

The rule as amended merely restates a statutory mandate in Pub. L. 98-224 superseding the current regulation, and no discretion is given to DOL in the implementation of the requirement. Pub. L. 98-224 is effective with respect to fiscal years beginning on or after October 1, 1984. Sec. 2, Pub. L. 98-224, 98 Stat. at 2486. Therefore, DOL for good cause finds that notice and public comment on the rule are impracticable, unnecessary, and contrary to the public interest. 5 U.S.C. 533(b)(3). Since the rule relieves somewhat the restriction on classification of training costs, and since Pub. L. 98-224 was effective on October 1, 1984, and permits no discretion on the part of DOL, DOL finds



that there is good cause to make the rule effective upon its publication in the *Federal Register*. 5 U.S.C. 553(d) (1) and (3).

#### Regulatory Impact:

This rule affects only the assignment of costs relating to youth training under JTPA grants to Governors. As such, it does not have the financial or other impact to make it a major rule, and, therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291, 3 CFR, 1981 Comp., p. 127.

This document was not preceded by a general notice of proposed rulemaking, and, therefore, is not a rule as defined in the Regulatory Flexibility Act. 5 U.S.C. 601(2) and 604(a).

#### Catalogue of Federal Domestic Assistance Number

This program is listed in the *Catalogue of Federal Domestic Assistance* at No. 17.250, "Job Training Partnership Act (JTPA)".

#### List of Subjects in 20 CFR Part 629

Grant programs, Labor, Manpower training programs.

#### Promulgation of Final Rule:

Accordingly, Part 629 of Chapter V of Title 20, Code of Federal Regulations is amended as follows:

#### PART 629—[AMENDED]

In § 629.38, paragraph (e)(2)(iii) is revised to read as follows:

#### § 629.38 Classification of costs.

- (e) \* \* \*
- (2) \* \* \*
- (iii)(A) Stipulates that full payment for the full unit price will be made only upon completion of training by a participant and placement of the participant into unsubsidized employment in the occupation trained for and at not less than the wage specified in the agreement; or
- (B) In the case of youth, payment for training packages purchased competitively pursuant to section 141(d)(3) of the Act shall include payment for the full unit price if the training results in either placement in unsubsidized employment of the attainment of an outcome specified in section 106(b)(2) of the Act.

(Sec. 7, Pub. L. 98-524, 98 Stat. 2435, 2491)

Signed at Washington, D.C., this 19th day of April, 1985.

Ford B. Ford,

Under Secretary of Labor.

[FR Doc. 85-10181 Filed 4-25-85; 8:45 am]

BILLING CODE 4510-30-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 660

[Docket No. 81N-0417]

#### Additional Standards for Anti-Human Globulin; OMB Approval of Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Office of Management and Budget (OMB) has approved the collection of information requirements in the biologics regulations concerning additional standards for Anti-Human Globulin. The agency is amending those regulations to reflect OMB's approval.

**EFFECTIVE DATE:** April 26, 1985.

#### FOR FURTHER INFORMATION CONTACT:

Joseph Wilczek, Center for Drug and Biologics (HFN-368), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of February 11, 1985 (50 FR 5574), FDA established additional standards for Anti-Human Globulin (21 CFR Part 660, Subpart F). In that document (50 FR 5578), FDA announced that it had submitted the final rule to OMB for approval of the collection of information requirements contained in §§ 660.51, 660.52, 660.53, 660.54, and 660.55.

OMB has approved the collection of information requirements under OMB control number 0910-0208. This document announces OMB's approval and amends the regulations to reflect that approval.

Because this amendment merely reflects OMB's approval of collection of information requirements, notice and public procedure and delayed effected date are unnecessary (5 U.S.C. 553 (b)(6) and (d)).

#### List of Subjects in 21 CFR Part 660

Biologics, Labeling.

## PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

§§ 660.51, 660.52, 660.53, 660.54, and 660.55 [Amended]

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 660 is amended in § 660.51 *Processing*, § 660.52 *Reference preparations*, § 660.53 *Controls for serological procedures*, § 660.54 *Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties*, and § 660.55 *Labeling* by inserting the number "0910-0208" at the end of the parenthetical statement at the end of each section. *Effective date.* April 26, 1985.

(Sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: April 19, 1985.

Mervin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-10092 Filed 4-25-85; 8:45 am]

BILLING CODE 4160-01-M

## OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

### 29 CFR Part 2200

#### Amendment of Review Commission Rules of Procedure to Clarify Commission Procedures Regarding the Issuance of Subpoenas and the Failure of Parties to File Briefs

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule.

**SUMMARY:** This document amends the rules of procedure of the Occupational Safety and Health Review Commission to delegate to its judges the function of signing subpoenas and to describe the action that may be taken if parties fail to respond to a briefing notice. The amendments are intended to clarify regulations at 29 CFR Part 2200.

**EFFECTIVE DATE:** April 26, 1985.

#### FOR FURTHER INFORMATION CONTACT:

Earl R. Ohman, Jr., General Counsel, Occupational Safety and Health Review Commission, 1825 K Street, NW., Suite 402, Washington, D.C. 20006, (202) 634-4015.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 12(g) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 661(f), by which the Review Commission is authorized to make such rules as are



necessary for the orderly transaction of its proceedings, the review Commission has promulgated Rules of Procedure at 29 CFR Part 2200.

Under section 12(i) of the Occupational Safety and Health Act, 29 U.S.C. 661(h), the Commission and its members are authorized to issue subpoenas. Rule 55(a) of the Review Commission's Rules of Procedure governs the issuance of subpoenas. In practice, under Rule 55(a), the Commission's judges issue subpoenas imprinted with the Chairman's signature. Consistent with the other duties of the Commission's judges that are described in section 12(j) of the Act, 29 U.S.C. 661(i), the Commission now delegates to its judges the purely ministerial function of signing the subpoenas.

Rule 93(d) of the Review Commission's Rules of Procedure governs the failure of parties involved in the Commission's proceedings to timely file briefs. The failure to timely respond to the Commission's briefing notice by a party whose petition for review has been granted has created uncertainty for other parties attempting to comply with the Commission's briefing schedule. It also has delayed adjudication of the case. The Commission has generally given parties a further opportunity to file a brief and indicated that if no response is received the direction for review may be vacated. The Commission may also vacate the direction if the petitioning party fails to respond. To clarify its practice, the Commission amends its Rules of Procedure to spell out what action it may choose to take if the parties fail to respond to a briefing notice. Because the rule changes are procedural, 5 U.S.C. 553(h)(3)(A) permits them to be effectuated without prior notice or public comment.

#### List of Subjects in 29 CFR Part 2200

Administration practice and procedure, Occupational safety and health.

#### PART 2200—[AMENDED]

1. For the reasons stated in the summary, 29 CFR Part 2200 is amended by revising § 2200.55(a) to read as follows:

§ 2200.55 Issuance of subpoenas; petitions to revoke or modify subpoenas; right to inspect or copy data.

(a) On behalf of the Commission or any member thereof, the judge shall, on the application of any party, issue to the applying party subpoenas requiring the attendance and testimony of witnesses and the production of any evidence, including relevant books, records,

correspondence or documents, in his possession or under his control. The party to whom the subpoena is issued shall be responsible for its service. Applications for subpoenas, if filed prior to the assignment of the case to a judge, shall be filed with the Executive Secretary at 1825 K Street, NW., Washington, D.C. 20006. After the case has been assigned to a judge, applications shall be filed with the judge. Applications for subpoenas shall be made ex parte. The subpoena shall show on its face the name and address of the party at whose request the subpoena was issued.

2. For the reasons stated in the summary, 29 CFR Part 2200 is amended by revising § 2200.93(d) to read as follows:

#### § 2200.93 Briefs before the Commission.

(d) *Consequences of late filing of brief.* The Commission may decline to accept a brief that is not timely filed. If a petitioning party fails to respond to a briefing notice or expresses no interest in review, the Commission may vacate the direction for review, or it may decide the case without that party's brief. If the non-petitioning party fails to respond to a briefing notice or expresses no interest in review, the Commission may decide the case without that party's brief. If a case was directed for review upon a Commissioner's own motion, and either party fails to respond to the briefing notice, the Commission may either vacate the direction for review or decide the case without briefs.

(Sec. 12(g), Occupational Safety and Health Act of 1970, 29 U.S.C. 661(f))

Signed this 19th day of April, 1985.

E. Ross Buckley,

Chairman.

Timothy F. Cleary,

Commissioner.

[FR Doc. 85-9963 Filed 4-25-85; 8:45 am]

BILLING CODE 7600-01-M

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[A-8-FRL 2821-6]

#### Approval and Promulgation of Implementation Plans; Montana; Colstrip Area Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** The Agency is approving the Colstrip nonattainment area plan for control of Total Suspended Particulate (TSP) emissions to meet the primary NAAQS for TSP as required under section 110, of the Clean Air Act. A proposal to approve this plan was published in the Federal Register on July 5, 1983, and again July 23, 1984, as a part of a package of Montana issues.

**EFFECTIVE DATE:** April 26, 1985.

**ADDRESSES:** Copies of the submittal are available at the following addresses:

Environmental Protection Agency,  
Montana Office, Federal Building,  
Drawer 10096, 301 South Park, Helena,  
Montana 59626  
Environmental Protection Agency,  
Region VIII, Air Program Branch, 1  
Denver Place, Denver, Colorado 80295  
Public Information Reference Unit, EPA  
Library, 401 M Street, SW.,  
Washington, D.C.  
Office of the Federal Register, Room  
8401, 1100 L Street, NW., Washington,  
D.C.

#### FOR FURTHER INFORMATION CONTACT:

Jay M. Sinnott, Environmental  
Protection Agency, Montana Office,  
Federal Building, Drawer 10096, 301  
South Park, Helena, Montana 59626,  
(406) 449-5486

**SUPPLEMENTARY INFORMATION:** In a March 4, 1980 notice of final rulemaking (45 FR 14036), EPA approved the Colstrip plan on the condition that the State issue a permit to Western Energy Company requiring that the Company carry to completion all of the activities set forth in the State's October 4, 1979 submission.

On September 21, 1981, the Governor submitted a copy of the permit issued to Western Energy Company in response to EPA's comments. The permit contains all of the needed requirements, and EPA proposed approval of the plan, along with a number of other Montana actions, on July 5, 1983 (48 FR 30696) and again on July 23, 1984 (49 FR 29622). No comment was received on the Colstrip plan following either of these notices.

#### Final Action

EPA is approving the Colstrip area plan, submitted by Montana, for attainment of the primary National Ambient Air Quality Standards for TSP.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

**Authority:** Secs. 110(a) and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410(a) and 7601(a)).



Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today). This action may not be challenged later in proceedings to enforce its requirements (see 307(b)(2)).

#### List of Subjects in 40 CFR Part 52

Air pollution control, Particulate matter, Incorporation by reference.

**Note.**—Incorporation by reference of the State Implementation Plan for the State of Montana was approved by the Director of the Federal Register on July 1, 1982.

Dated: April 12, 1985

Lee M. Thomas,  
Administrator.

#### PART 52—[AMENDED]

Title 40, Part 52 of the Code of Federal Regulations is amended as follows:

##### Subpart BB—Montana

1. In § 52.1370 paragraph (c)(17) is added as follows:

##### § 52.1370 Identification of plan.

(c) \* \* \*

(17) On September 21, 1981 the Governor submitted a permit which had been issued to the Western Energy Company as required in the conditional approval of the Colstrip TSP plan.

2. Section 52.1380 is amended by revising the introductory paragraph and paragraph (a) and by removing and reserving paragraph (b) (which would remove the condition of approval of the above regulations):

##### § 52.1380 Control strategy: Total suspended particulates.

Part D—Conditional Approval—The Butte plan is approved provided that the following condition is met:

(a) For Butte, by February 15, 1981, the State will submit a revised airborne particulate regulation as specified in their October 4, 1979, submittal to EPA.

(b) [Reserved]

(Sec. 110 of the Clean Air Act, as amended)

[FR Doc. 85-9425 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

#### 40 CFR Part 81

[A-8-FRL-2821-7]

#### Designation of Areas for Air Quality Planning Purposes; Montana

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Agency is approving the redesignation of the Colstrip Area from nonattainment to attainment of Federal Primary Total Suspended Particulate (TSP) standards. The State of Montana requested this redesignation on October 17, 1984 as authorized under section 107 of the Clean Air Act.

**EFFECTIVE DATE:** This action will take effect June 25, 1985 unless notice is received within 30 days that adverse or critical comments will be submitted.

**ADDRESSES:** Copies of documents supporting Montana's request are available for public inspection at the following addresses:

Environmental Protection Agency,  
Montana Office, Federal Building,  
Room 292, 301 South Park, Helena,  
Montana 59626

Environmental Protection Agency,  
Region VIII, Air Programs Branch, 1  
Denver Place, Denver, Colorado 80295.

#### FOR FURTHER INFORMATION CONTACT:

Jay M. Sinnott, Environmental Protection Agency, Montana Office, Federal Building, Drawer 10096, 301 South Park, Helena, Montana 59626, (406) 449-5486.

**SUPPLEMENTARY INFORMATION:** On October 17, 1984, Montana submitted a request to redesignate the Colstrip area from nonattainment to attainment of the primary TSP standards. This submission includes monitoring and modeling information to support the request.

#### Background

The Colstrip nonattainment area, so designated in a state submission of January 6, 1978, is an area of approximately 120 square miles surrounding the community of Colstrip (population 1,476). The main sources of particulate emissions in the area are coal strip mines operated by the Western Energy Company and the Peabody Coal Company; construction activity at Montana Power Company's Colstrip unit 3 and 4 coal-fired power plants; road dust and highway construction activities.

The agency proposed approval of Montana's attainment plan on July 23, 1984. A previous conditional approval on March 4, 1980 called for submission of a permit issued to Western Energy Company which includes the emission controls required to achieve attainment. This permit was submitted September 21, 1981. EPA is taking final action approving Montana's attainment plan in a separate notice published in today's Federal Register.

Highway construction in Colstrip has been completed and power plant construction activity at the near-

complete power plants has decreased dramatically.

The most recent eight quarters of data, ending March 31, 1984, reveal a maximum annual geometric mean of 43  $\mu\text{g}/\text{m}^3$  and a second highest 24-hour level of 191  $\mu\text{g}/\text{m}^3$ , well below the respective primary standards of 75 and 260  $\mu\text{g}/\text{m}^3$ . This data was collected at six (6) sampling sites which clearly meet siting criteria and are representative of the area.

A modeling study predicts that no violations will occur in the Colstrip area throughout the projected period of peak mining activity.

#### Final Action

The Agency is approving Montana's request to redesignate the Colstrip area from nonattainment to attainment of primary TSP National Ambient Air Quality Standards.

The request is being approved without a prior proposal because the action is expected to be noncontroversial and no adverse comments are anticipated. If significant adverse or critical comment is received a notice will be published withdrawing this action and another notice will appear proposing to approve an action and establishing a comment period.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities (see 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

**Authority:** Secs. 107(d)(5), 110(a) and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410(a) and 7601(a)).

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today). This action may not be challenged later in proceedings to enforce its requirements (See 307(b)(2)).

#### List of Subjects in 40 CFR Part 81

Air pollution control, National Parks, Wilderness areas.

Dated: April 12, 1985.

Lee M. Thomas,  
Administrator.

#### PART 81—[AMENDED]

Part 81 of Chapter 1, Title 40 of the Code of Federal Regulations is amended by revising the TSP portion of the table in § 81.327 as follows:



## § 81.327 Montana.

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
<b>Montana-TSP</b>				
City of Missoula	X			
Colstrip area		X		
City of Columbia Falls	X			
Missoula area		X		
Butte area	X			
Billings area		X		
Great Falls area		X		
East Helena area		X		
Remainder of State				X

<sup>1</sup> EPA designation replaces State designation.

[FR Doc. 85-9424 Filed 4-25-85; 8:45 am]

BILLING CODE 6550-50-M

## 40 CFR Part 723

[OPTS-50032B; 2742-1]

**Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kg or Less Per Year**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Section 5(a)(1)(A) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. EPA is granting a limited exemption under section 5(h)(4) from the requirements of section 5(a)(1)(A) for persons who manufacture certain new chemical substances in quantities of 1,000 kilograms or less per year. To ensure that these chemical substances will not present an unreasonable risk, EPA has included procedural safeguards, including a 21-day review, and other conditions in the exemption.

**DATE:** This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on May 10, 1985. This rule is effective June 10, 1985.

**FOR FURTHER INFORMATION CONTACT:**

Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C., 20460  
Toll-free: (800-424-9065).  
In Washington, D.C.: (554-1404).  
Outside the USA: (Operator 202-554-1404).

**SUPPLEMENTARY INFORMATION:** OMB control number 2070-0012.

**I. Background**

**A. Introduction**

Under section 5(a)(1)(A) of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA 90 days before manufacture or import begins. A new chemical substance is any chemical substance that is not on the Chemical Substance Inventory compiled by EPA under section 8(b) of TSCA.

The requirement to submit premanufacture notices (PMNs) for new chemical substances became effective on July 1, 1979, 30 days after publication of the Initial Inventory. EPA issued final Premanufacture Notice Requirements and Review Procedure, published in the *Federal Register* of May 13, 1983 (48 FR 21722). In the *Federal Register* of September 13, 1983 (48 FR 41132), the Agency clarified certain provisions of the rule, made a non-substantive amendment to the timing of the submission of the notice of commencement of manufacture, and stayed other provisions of the rule. The rule became effective October 26, 1983. Since the beginning of the program in 1979, EPA has reviewed more than 4,000 PMNs.

Section 5(h)(4) of TSCA allows the Administrator, upon application and by rule, to exempt a new chemical substance or category of new chemical

substances from any requirement of section 5 if he or she determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment. The Agency issued an exemption for certain chemical substances used in or for instant photographic film articles published in the *Federal Register* of June 4, 1982 (47 FR 24308), and an exemption for new polymeric substances which was published in the *Federal Register* of November 21, 1984 (49 FR 46066). With this notice, the Agency is issuing an exemption for certain low volume chemical substances.

This exemption was developed in response to petitions from the Chemical Manufacturers Association (CMA) and other industry trade groups. Notice of receipt of the CMA and other petitions was published in the *Federal Register* of November 3, 1981 (46 FR 54688); proposed rules were published in the *Federal Register* of August 4, 1982 (47 FR 33896, 47 FR 33924). These rules, which would have exempted certain site-limited intermediates and low volume substances, were proposed as § 723.10 of Subpart A. The final rule is promulgated as § 723.50 of Subpart B, but includes only substances manufactured or imported at 1,000 kilograms or less per year.

The 60-day comment period on the proposals ended on October 4, 1982. EPA received 52 comments on the site-limited intermediate and low volume proposal from trade associations, chemical manufacturers, an environmental organization, and other interested persons. At the request of the Natural Resources Defense Council and other groups, a public hearing was held on November 1, 1982, in Washington, D.C. Seven organizations or individuals made oral comments on the proposal at the hearing. EPA reopened the public comments period at the hearing, extending it for 30 days, to give participants at the hearing an opportunity to answer questions from EPA on their comments. Seven organizations provided comments during the extended period.

EPA has summarized its response to the major public comments received during the rulemaking. This summary, together with copies of the public comments and a transcript of the hearing, is included in the public record.

**B. Exemption Requests**

The CMA petition, received on May 21, 1981, requested exemptions for:

1. Site-limited intermediates.



2. Chemical substances produced in quantities of 25,000 pounds or less per year.

3. Polymers whose precursor monomers are on the TSCA Inventory.

In addition, CMA requested an exemption that would authorize EPA to allow manufacture of new chemical substances of low concern before the end of the 90-day PMN review period. CMA also requested that EPA issue regulations establishing a procedure for handling individual section 5(h)(4) exemption applications.

In support of its petition, CMA argued that the requirements of section 5 of TSCA inhibit innovation in the chemical industry. According to CMA, the requested exemptions would significantly reduce the impact of section 5 on innovation and, by requiring review by an industry "qualified expert," encourage industry to conduct adequate risk assessments before introducing new chemical substances into commerce. CMA also stated that its proposal embodied a "pay as you go" approach. Under such an approach, PMNs on exempted chemical substances would be deferred until the cost of PMN submission would be less burdensome and until more comprehensive information developed by manufacturers might be available for EPA review.

EPA subsequently received petitions from the Synthetic Organic Chemical Manufacturers Association (June 28, 1981) and the Dyes Environmental and Toxicological Organization (July 10, 1981) requesting an exemption for the same categories of chemical substances proposed by CMA. In addition, seven trade organizations submitted endorsements of the CMA petition.

### C. Alternatives Proposed

In response to the petitions from CMA and other groups, EPA began separate rulemakings for polymers and site-limited intermediates/low volume chemicals. This rule addresses only chemical substances produced at 1,000 kilograms or less per year. The polymer exemption rule was published in the *Federal Register* of November 21, 1984 (49 FR 46066).

After reviewing comments from both industry and the public, EPA has decided not to pursue at this time a rule to exempt site-limited intermediates and chemical substances produced in quantities of between 1,000 and 10,000 kilograms per year. Industry commenters stated that the exemption criteria for these categories (particularly the qualified expert provisions) were overly burdensome, and that the exemption did not provide significant

relief. The Agency, however, determined that it could not reduce the procedural safeguards in the rule and still make the finding of no unreasonable risk. At the same time, public interest groups questioned the legal basis of the exemptions. Therefore, EPA has decided to issue a more limited exemption applying only to substances produced at 1,000 kilograms or less per year.

EPA also has decided not to pursue at this time a rule to shorten the PMN review period, because (1) it believes that the exemptions for low volume chemical substances and polymers will substantially reduce or eliminate the need for this exemption, and (2) there is a serious question as to whether TSCA permits EPA to allow early manufacture by either a rule or a policy statement. In addition, because of limited resources, EPA has decided not to develop general section 5(h)(4) procedural rules at this time.

## II. Final Exemption

### A. Summary of the Rule

The final rule exempts certain low volume chemical substances from premanufacture notification requirements of section 5 of TSCA. The basic outline of the rule is described below.

Manufacturers or importers of a new chemical substance produced at 1,000 kilograms or less per year may submit a brief exemption notice to EPA, in lieu of a full PMN, 21 days before manufacture. The notice must include chemical identity, a description of use, site of manufacture, and test data in the submitter's possession or control. EPA will review the notice and declare a chemical substance ineligible for the exemption if the Agency determines that the substance (or metabolites, environmental transformation products, impurities, or byproducts) may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal, or that serious unresolved issues concerning potential risks require further review. If EPA does not find the substance ineligible, manufacture may begin at the end of the review period. Manufacturers must submit another exemption notice before use or site or manufacture changes; only one manufacturer may make a given chemical substance under this exemption.

The rule also establishes procedures by which EPA can revoke an exemption for a specific chemical substance after manufacture has begun. EPA will revoke an exemption if new information

indicates that the chemical substance does not meet the criteria for an exemption.

### B. Discussion of the Final Rule

The final rule adopts most of the provisions concerning substances manufactured at 1,000 kilograms per year or less in the proposed rule published on August 4, 1982. This unit of the preamble clarifies several areas of confusion identified by public commenters and discusses the differences between the final rule and the proposal.

#### 1. Scope of Rule

As explained in Unit I.C of this preamble, this final rule does not include exemptions for site-limited intermediates or substances produced at between 1,000 and 10,000 kilograms per year. It exempts from the full PMN requirements only certain substances produced in quantities of 1,000 kilograms or less per year.

#### 2. Length of Review Period

The proposed rule would have required that companies notify EPA 14 calendar days before manufacturing a new chemical substance under the exemption. In the final rule, companies are required to notify EPA 21 calendar days before manufacture begins.

EPA recognizes that one of the major benefits of this exemption is that it allows companies to respond more rapidly to market demand and to introduce new chemical substances more quickly into commerce. Extending the review period from 14 to 21 calendar days will to a certain extent reduce this benefit. However, after carefully reviewing public comments and its experience in the premanufacture notice review process, the Agency has concluded that 14 calendar days will not be long enough to review exempt chemical substances adequately. Instead, 21 days is the minimum reasonable period in which EPA can review an exemption candidate and, if necessary, inform the manufacturer that it is not eligible for the exemption. For this reason, the review period was extended.

#### 3. Exclusions

EPA will exclude specific substances from the exemption if, during its 21-day review, it concludes that the substances themselves, or reasonably anticipated metabolites, environmental transformation products, byproducts, or impurities, may cause serious acute or chronic effects in humans or significant environmental effects under reasonably



anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal.

Several commenters asked for clarification of these standards.

a. *Serious acute or chronic human effects.* Several commenters asked for further explanation of the standard for excluding chemical substances capable of causing "serious acute effects" and "serious chronic effects." To clarify this standard, EPA has revised these definitions to include "disfigurement" and "severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities," as well as death and severe or prolonged incapacitation. This revised definition would include any generally recognized adverse health effect (e.g., neurotoxic effects, liver and other organ toxicity, reproductive toxicity, mutagenicity, carcinogenicity, teratogenicity, fetotoxicity, skin sensitization, and severe skin and eye irritation). The modification makes it clear that a chemical substance could be excluded because of potential for non-life-threatening as well as life-threatening effects.

Several commenters also requested that EPA clarify the list of examples of serious acute or chronic effects contained in the preamble to the proposal. EPA intended that the list illustrate the kinds of possible effects that might cause the Agency concern and that could disqualify a substance from the exemption. EPA does not expect that exempt substances will not have any of these effects under any circumstances. However, if EPA concludes that a substance may cause any of these effects, the substance would not be eligible for the exemption unless the conditions of manufacture, processing, use, and disposal were such that serious adverse effects would not occur.

b. *Significant environmental effects.* The proposal defined "significant environmental effects" as "injury to the environment which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or causes the loss of a member of a rare or endangered species." The Agency received numerous comments on this definition, many of them expressing the concern that potential for any injury would lead to the exclusion of a substance from the exemption. Also, several commenters stated that the manufacturer might have no way to know whether the substance might threaten a single member of an endangered species.

In response to these comments, § 723.50(b)(11) of the final rule defines "significant environmental effects" as:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society,

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year, or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. "Endangered" or "threatened" species are those species identified by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

This change is intended to clarify the point that potential for insignificant or trivial injury to individual environmental organisms or to environmental resources would not disqualify a substance. As EPA explained in the preamble to the proposed rule, it does not intend to exclude all chemical substances that might cause any harm to any organism. Rather, the exclusion is directed toward "significant" environmental effects, both acute and chronic. The significance of environmental effects must be viewed in terms of the extent of the environmental damage, the potential recovery or repairability of the damage, and the degree to which the damage will impair the utility or function of the environmental unit affected.

Examples of significant environmental effects include direct effects on resources of demonstrable value, such as a fish kill reducing the value of a commercial fish population for a single generation, or a long-term reduction in a fish population over several generations. They also include indirect effects, such as long-term reduction in soil fertility; ecologically significant changes in species' interrelationships, e.g., excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems; and ecologically significant interference with critical biochemical cycles, such as the nitrogen cycle. This list is illustrative and is not intended to be all-inclusive. However, any substance capable of exhibiting these or comparable effects under reasonably anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal would not be eligible for an exemption.

Several commenters suggested that EPA modify the definition of significant environmental effects so that it was the same as the definition of substantial risk

in EPA's policy statement implementing section 8(e) of TSCA published in the *Federal Register* of March 16, 1978 (43 FR 11110). Section 8(e) of TSCA requires manufacturers, processors, and distributors to notify EPA of any information that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. However, EPA decided not to adopt the section 8(e) standard in this exemption; this standard was developed to ensure that EPA learned of known hazards associated with existing chemicals likely to be distributed widely in the environment. The Agency does not believe that this standard would be adequate to support a "no unreasonable risk" finding under TSCA section 5(h)(4). However, it should be clear that any environmental risk that would trigger a section 8(e) substantial risk notification would exclude a substance from this exemption if EPA concluded that such risks may occur under reasonably anticipated conditions of manufacturing, processing, distribution in commerce, use, or disposal.

c. *Byproducts and impurities.* The proposal excluded chemical substances from the exemption if there was a reasonable basis to conclude that byproducts of manufacture, processing, distribution in commerce, use, or disposal may have serious acute or chronic effects in humans or significant environmental effects under reasonably anticipated conditions of exposure. The final rule also excludes chemical substances if EPA concludes that impurities in the substance may cause such effects under reasonably anticipated conditions of exposure. This requirement was added because on several occasions the Agency has taken action on new chemical substances because of impurities. Therefore, EPA believes that it is necessary to consider impurities in its review and to exclude new substances because of potential risks posed by impurities.

#### 4. Information Requirements

The final rule retains the basic requirements concerning the information the manufacturer must provide in the exemption notice. However, it modifies the requirements for chemical identity and use descriptions. These changes are discussed below.

a. *Test data.* Companies intending to manufacture a substance under the exemption must include test data in the submitter's possession or control that are related to the effects of the chemical substance on health and the



environment. This includes physical-chemical properties and environmental fate data relevant to risk assessment (e.g., vapor pressure, partition coefficient, biodegradation data) as well as toxicological data. Where a company performs tests to support an exemption, EPA recommends that it follow the testing guidelines developed by the Organization for Economic Cooperation and Development or EPA's Office of Toxic Substances [see EPA, "Health Effects Test Guidelines," EPA 560/6-82-001].

The term "possession or control" was defined in § 720.3(y) of the final PMN rule (48 FR 21722). However, that provision was stayed in the Federal Register of September 13, 1983 (48 FR 41132) and a new definition has been proposed in the Federal Register of December 27, 1984 (49 FR 50201). Until the new definition becomes final, exemption notice submitters should follow the September 13, 1983 clarification (48 FR 41132) and the preamble to the proposed definition (49 FR 50201).

b. *Data on impurities.* In the proposed rule, manufacturers were not required to provide EPA with any information on impurities. This information, however, is required in notices submitted under section 5(a)(1) of TSCA as part of the description of chemical identity. On several occasions it has proved critical in the Agency's assessment of risks posed by a new chemical substance. Therefore, EPA believes that it is necessary to require information on impurities in the final exemption rule. Section 723.50(e)(1)(iii)(D) of the final rule requires the manufacturer to identify impurities anticipated to be present in the exempt substance and their weight percent in the total substance. If there are unidentified impurities, the notice must include an estimate of their total weight percent. Information on impurities must be provided to the extent that it is known to or reasonably ascertainable by the submitter.

c. *Polymer identity.* The final rule has also been revised so that information required on polymer identity is the same as that required in § 720.45 of the PMN rule. To the extent the information is known or reasonably ascertainable, companies must indicate the typical composition of each monomer and other reactants used in the polymer (by weight percent of total monomer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram. The notice must also provide estimates of the minimum number-average molecular weight of the

polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, and it must describe how the estimates were made. In the section 5 notice review program, EPA has frequently found this information important in assessing new polymers and in characterizing their potential risks. For this reason, EPA believes that such information is necessary in exemption notices as well as in section 5(a)(1) notices.

For guidance on providing information on polymer identities, companies should refer to EPA's clarification of the PMN notification requirements (48 FR 41132).

d. *Generic name.* In the proposal, there were no provisions for developing generic chemical names to protect confidential chemical identities. However, EPA intends to publish the identity of chemical substances manufactured under the exemption (see unit II.D of this preamble); therefore, the final rule requires manufacturers of exempt chemical substances to develop and submit to EPA generic chemical names masking the identity of the substance if they claim the substance's specific identity as confidential. The name must be only as generic as necessary to protect the confidential chemical identity and should reveal the specific chemical identity to the maximum extent possible.

It is important for manufacturers who claim chemical identity confidential to provide generic names: if a generic name is not provided, EPA may develop its own name and publish it on the list of exempted chemicals. This name may be less acceptable to the manufacturer than one it could have developed. For further discussion of generic names and confidentiality, see Unit II.B.10 of this preamble.

e. *Description of use.* In the proposal, manufacturers of low volume chemical substances would have been required to provide a brief use description by function and application in their exemption notices. Examples of function/application use descriptions are: Surfactant in automobile spray wax, colorant for paper and other cellulose, and antioxidant in fuel oils and lubricants.

Section 723.50(e)(1)(iv) generally retains this requirement and further specifies that the submitter must indicate whether the use or uses are industrial, commercial, or consumer. However, the final rule drops the requirement that the use description "must be specific enough to indicate the typical circumstances of exposure, including routes of exposure, associated with new chemical substances." This

sentence raised concern among commenters, some of whom believed it implied the need for extensive and detailed descriptions. EPA eliminated it from the final rule because it believes that a description of use by function and application will generally provide enough information to determine circumstances of exposure. However, when EPA does not have sufficient information on use to characterize exposure, the exemption may be denied if warranted by toxicity concerns.

The use description requirements in the final rule are consistent with those of the TSCA section 5(a)(1) notice form for new chemical substances. For guidance on developing use descriptions, or on providing other information in the exemption notice, such as chemical identity, see the EPA "Instructions Manual for Premanufacture Notification of New Chemical Substances," available from the Office of Toxic Substances, TSCA Assistance Office, and EPA's Federal Register notice clarifying the PMN rule (48 FR 41132).

Several commenters suggested that use descriptions should be required only if the uses are known to the manufacturer. This suggestion was not adopted in the final rule. EPA believes that it is reasonable to require manufacturers, as a condition of the exemption, to ascertain the uses to which their products will be put and to provide that information to EPA. Because the use must be described only in relatively general function/application terms EPA believes that this requirement will not be burdensome.

f. *Exposure and other data.* Companies intending to manufacture a substance under this exemption are not required to provide information on exposure or exposure controls. However, they should recognize that EPA, without specific information on exposure, release, and controls will make reasonable assumptions, based on use, in reviewing the substance. Where there may be some concern for toxicity, manufacturers may wish to provide EPA with more information on exposure, release, or controls. In many cases, this information may eliminate potential EPA concerns. However, § 723.50(e)(1)(viii) requires that, where a manufacturer provides information on exposure controls or other controls to support its exemption notice, the manufacturer must maintain those controls throughout the exemption.

g. *Sanitized copy of notice.* The final rule requires the submitter to provide a sanitized copy of the notice. This provision, while not in the original



proposal, is included in the final rule to safeguard the confidentiality of the submission. This sanitized copy submission requirement is similar to requirements contained in the PMN rule (40 CFR 720.80(b)(2)), the polymer exemption rule (40 CFR 723.250), and the exemption rule for substances used in or for the manufacture or processing of instant photographic and peel-apart film articles (40 CFR 723.175).

#### 5. Customer Notification

The proposal and the final rule require companies holding an exemption to submit a new exemption notice before manufacturing the exempt chemical substance for a use not described in the original notice. (This would include changes from one class of use to another—e.g., from industrial to consumer uses—as well as changes in function/application within these classes.)

Several commenters stated that this requirement raised difficulties because companies might not know of new uses developed by their customers. One commenter—an industry trade association—suggested that EPA could address these difficulties by requiring the manufacturer to notify customers of use restrictions. Section 723.50(j) of the final rule adopts this suggestion. The rule does not specify how companies must notify customers of use restrictions, but rather leaves the form of notification up to the exemption holder. However, as part of the rule's recordkeeping requirements (see Unit II.B.7 of this preamble), manufacturers are expected to keep records documenting notification.

EPA believes that this requirement is necessary because EPA's 21-day review will be based on the use description in the exemption notice. A change in use may lead to substantially different conditions of exposure. Therefore, EPA believes that it is appropriate to require the manufacturer to take reasonable steps to ensure that the exempt substance is used as intended (and as reviewed by EPA).

#### 6. Notification of Changes in Site of Manufacture or Use

The proposal would have required manufacturers to renotify EPA if they manufactured a new chemical substance at a site of manufacture or for a use not reported in the exemption notice. Several commenters suggested that this requirement was unnecessary. Site of manufacture and use, however, will be important elements in EPA's 21-day review; changes in site or use might lead to considerably different exposure. Therefore, EPA believes that it is

necessary to retain the requirement that companies submit a new exemption notice before either of these elements changes.

Several commenters suggested that it would be unnecessarily burdensome to comply with these renotification requirements. EPA, however, believes that the burden should be minimal. EPA assumes that submitters will be able to identify likely sites of manufacture and uses with reasonable accuracy in their original notices. Therefore, companies will have to renotify EPA infrequently.

#### 7. Recordkeeping

The proposed rule required manufacturers to maintain records pertaining to production volume for 5 years after the final date of manufacture of the exempt substance. Many commenters pointed out that this requirement could mean that records might have to be retained almost indefinitely; commenters also suggested that this requirement was particularly difficult for production volume records, which are typically kept for only 5 years.

In response, EPA has modified the recordkeeping requirements. Section 723.50(o)(1) of the final rule requires manufacturers of exempt chemical substances to maintain production volume records for 5 years after the date of their preparation. In other words, exemption files must include production volume records for the previous 5 years. Manufacturers must also maintain (1) documentation of information in the exemption notice, and (2) documentation of compliance with the terms of the exemption. Documentation of compliance includes available records documenting site of manufacture and uses, customer notifications, etc. Like the production volume records, documentation of information in the notice and of compliance must be retained for 5 years after its preparation.

#### 8. Standards for Denial of Exemption

The proposal stated that EPA would deny an exemption for a chemical substance during its abbreviated review if "the new chemical substance does not meet the terms of this section, or [if] unresolved issues concerning toxicity or exposure require further review." Several commenters suggested that it was inappropriate for EPA to deny an exemption simply because of "unresolved issues"; EPA should deny an exemption only when there was clear evidence that a substance was not eligible.

EPA disagrees with this comment and is retaining the proposed language in §723.50(g)(1) of the final rule, with minor

editorial modifications. EPA has based its "no unreasonable risk" finding in part on its experience in the PMN process, which indicates that within 2 to 3 weeks of notice submission it can identify problematic chemical substances requiring more detailed review. In some cases, such substances are selected for more detailed review because of "serious unresolved issues," rather than because of affirmative evidence that a substance may be a problem. EPA believes that its ability to deny an exemption for the same reasons is an essential element of the rule and the no unreasonable risk finding.

EPA would not deny an exemption under this standard simply for speculative reasons. Instead, exemptions would be denied where serious concerns were raised, and more time or information was necessary to address them. For example, a chemical substance might be an analogue of a suspected carcinogen, or it might raise other toxicity concerns, but the potential for exposure might be unclear. This would be a particular concern where limited information was provided by the notice submitter or exposure fell outside the control of the manufacturer. In such cases, further review might be necessary to ensure that the manufacture and use of the exemption candidate would be safe.

In some cases, the submitter may be able to provide EPA with information during the 21-day review period that would resolve an issue, and manufacture would not be delayed. However, where a serious issue concerning the safety of the chemical substance cannot be resolved during the review period, it is important that EPA have the authority to reject the exemption.

#### 9. Revocation

The proposal established procedures by which EPA could revoke an exemption for a given chemical substance after the review period ended. EPA would take such an action if new information indicated that the substance did not meet the terms of the exemption.

In general, EPA has retained the basic approach of the proposal, although it has modified the specific terms in several respects. Under the final rule, if EPA makes a preliminary determination that the substance does not meet the terms of the exemption after the review period has ended, it will notify the manufacturer by certified letter. EPA might reach this conclusion if new information indicated that the substance was not eligible (e.g., new data might be received on the exempt substance



showing significant risk potential). The manufacturer will have 15 days from written notification to submit objections to the determination or an explanation of its diligence and good faith in attempting to meet the terms of the exemption. If the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and submits objections or an explanation or both within 15 days, it may continue to manufacture, process, distribute in commerce, and use the substance while EPA considers the objections or explanation.

If a manufacturer is not manufacturing, processing, distributing in commerce, or using the chemical substance at the time it receives notification from EPA, it cannot resume manufacture until EPA determines that the substance meets the terms of the exemption or until a PMN has been submitted and the notice review period has ended without action by EPA.

This provision modifies the proposal which would have allowed the manufacturer to continue commercial activities after notification only if it were manufacturing the substance at the time of notification. Several commenters on the proposal suggested that these standards were unfair to batch processors who might not be in production at the time they received a notice of ineligibility. EPA believes it has addressed this problem by expanding the provision to allow manufacture to continue if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification. Thus, a batch manufacturer would not be adversely affected if it is between batches but still processing, distributing, or using the chemical substance previously produced. Although some companies will still be at a disadvantage under this approach, EPA believes that ineligible chemical substances should not be manufactured under an exemption. For this reason, the Agency believes that it is inappropriate to allow companies to begin manufacturing a substance under an exemption after information has been received indicating the substance is not eligible. The costs associated with this requirement should be minimal, because revocation procedures will probably have to be invoked only infrequently.

Several commenters stated that a 15-day period is not adequate to allow objections to be filed. In the final rule, EPA has modified this provision somewhat, requiring a response within 15 days of written instead of telephone

notification. In its written notification, the Agency intends to provide specific questions about the substance's eligibility, so that the manufacturer will be able to respond to EPA's particular concerns. EPA believes that 15 days is adequate time for the manufacturer to submit objections and/or an explanation of its due diligence and good faith efforts to meet the terms of the exemption.

Under the final rule, like the proposal, EPA will respond to the manufacturer's objections and explanations within 15 days. If EPA determines that the substance meets the terms of the exemption, the manufacturer could continue or resume manufacture under the exemption. If EPA determines that, while the substance does not meet the terms of the exemption, the manufacturer acted with due diligence and in good faith to meet the terms of the exemption and the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification, the manufacturer may continue to manufacture, process, distribute in commerce, or use the substance if it submits a PMN under section 5(a)(1) of TSCA and the PMN rule within 15 days of the final notification by EPA. If such a manufacturer were to continue to manufacture, process, distribute in commerce, or use the substance without submitting a PMN, EPA would bring an enforcement action.

If EPA determines that, despite the company's objections or explanation, the manufacturer did not act diligently and in good faith, the company must cease manufacture, processing, distribution in commerce, and use within 24 hours of telephone notification. This provision slightly modifies the proposal requirements for companies determined by EPA to be acting without due diligence or in bad faith. Under the proposal, such companies would have been required to cease manufacture within 24 hours of EPA's initial notification. Under the final rule, these companies may continue commercial activities if they file objections.

In determining whether a manufacturer exercised due diligence and good faith in attempting to comply with the rule, the Agency would consider many factors, and decisions would be made on a case-by-case basis as an exercise of the Agency's discretion. For example, a manufacturer would not be considered to have exercised due diligence and to have acted in good faith if it (1) deliberately falsified information in the exemption

notice, (2) failed to provide relevant toxicity data on the new chemical substance in its possession or control to EPA, or (3) knowingly changed the uses described in the notice after beginning manufacture.

Action under this provision of the rule would not prevent EPA from using its authority to bring an injunctive action under section 17 of TSCA to prevent further manufacture, or, if the substance presents an imminent hazard, action under section 7 of TSCA. In addition, any manufacturer who failed to meet the terms of the exemption intentionally or who submitted false or misleading information would be subject to an enforcement action.

#### 10. Confidentiality

Section 723.50(k) of the final rule specifies confidentiality procedures. These procedures are essentially the same as those in the proposal and in § 720.80 of the PMN rule. They take into account various requirements under the Act, including the need to provide nonconfidential information to the public, give EPA information it needs to respond to Freedom of Information Act requests, and allow persons to assert claims of confidentiality with minimum burden.

Under this exemption, a person may assert a claim of confidentiality for any information submitted to EPA. To do so, submitters must clearly indicate on the exemption notice or attached document (e.g., by circling, underlining, or bracketing) the information that they wish to claim as confidential. Only the information claimed as confidential should be identified as confidential. A submitter should not simply stamp "confidential" on the page which contains both confidential and nonconfidential information.

As discussed in Unit II.B.4.d of this preamble, § 720.50(k)(3) of the final rule requires that submitters provide a sanitized copy of the exemption notice in which all confidential information has been deleted. The final rule also requires submitters to develop and submit generic chemical names if they claim chemical identity confidential. (See Unit II.B.4.d.) In some cases, companies may develop a generic name that EPA believes is more generic than necessary to protect confidential chemical identity. In this case, EPA, using the procedures in § 720.85 of the PMN rule, will propose to the submitter a more specific name. If that name is unacceptable, the submitter must explain why EPA's name is not sufficiently generic to protect confidential chemical identity and propose an alternative. EPA



will publish the submitter's alternative name if it is acceptable. Otherwise, EPA will use for publication in the Federal Register the generic name it devised 30 days after giving notice to the submitter.

Sanitized copies of the exemption notices will be placed in the public file. The generic names will be maintained on a list of exempted substances, which EPA will update once a month. These updates will be published monthly in the Federal Register and periodically in the *TSCA Chemicals-in-Process Bulletin*.

### III. Major Issues

#### A. Volume Limits for Low Volume Chemical Substances

The final rule retains the proposed 1,000 kilogram per year limit for low volume chemical substances, but as explained in Unit LC of this notice, the final rule does not retain the greater than 1,000 kilogram per year production volume limit category.

EPA selected 1,000 kilograms per year because it is high enough to provide relief to a significant number of new chemical substances (approximately 20 percent of new chemical substances), while low enough to set a reasonable bound on possible risks. EPA is convinced that the safeguards built into the low volume exemption are adequate to protect against unreasonable risks at 1,000 kilograms per year, particularly with the extension of the review period to 21 days. Furthermore, the 1,000 kilograms or less per year limit was chosen because it is consistent with the volume trigger for full new chemical notification under the European Economic Community's Sixth Amendment.

#### B. Exclusion of High-Risk Chemical Categories

In the proposal, EPA suggested as an alternative that a list of high-risk chemical categories, based on structure, be developed. Individual new chemical substances falling into these categories would not be eligible for the exemption. The Dyes Environmental and Toxicology Organization, Inc. (DETO), in effect suggested this approach in its exemption petition for dyes when it stated that EPA might consider excluding benzidine, o-tolidine, and o-dianisidine-based dyes, and dyes containing N-N-dimethyl-4-aminobenzene analogues. The basis for this exclusion would be structure-activity information and test data which suggest that individual members of these categories might cause serious chronic health effects. Several commenters suggested that such an approach would

be advisable and would significantly strengthen the exemption.

EPA did not adopt this approach because it would be unnecessarily resource-consuming to develop a list of excluded categories of chemical substances. EPA believes that any general list of categories would provide no more protection than that already provided in the proposed rule by EPA's 21-day review. New chemical substances belonging to highly suspect classes, such as the classes identified by DETO, would be eliminated unless exposure information provided by the submitter demonstrated their safety under conditions of manufacture and use.

#### C. Subsequent Manufacturers

Under the final rule, only one manufacturer is allowed to manufacture a given substance under the exemption. Subsequent manufacturers of the same chemical substance would not be eligible for the exemption; they would be required instead to submit a premanufacture notice. This requirement is necessary because the risk assessment for the exemption assumes that total production of chemical substances in the category will not exceed the production volume limit of 1,000 kilograms per year.

Several commenters on the proposal criticized this approach on the grounds that it could result in unwarranted administrative complexities and that it might delay manufacture. As an alternative, commenters suggested that EPA allow subsequent manufacture under the exemption. EPA would have the opportunity to review the exemption notice and revoke the exemption for all exemption holders if it identified any concerns.

EPA rejected this approach because it could allow the aggregate production volume to grow well beyond the low volume limit without full premanufacture review. The exemption is based on the premise that the exempted substances will in fact be low volume—that is, below 1,000 kilograms per year. Even though it appears relatively unlikely that second or third manufacturers would produce the same substance under a given low volume exemption, this possibility could theoretically lead to the production of an exempt substance at volumes many times greater than the exemption volume limit. Also, it would be possible for companies to circumvent the volume limit by buying an exempt substance from several different manufacturers or importers, yet the substance could still be processed or used at a single site. EPA does not believe that the 21-day

review will be adequate to identify such situations consistently. For these reasons, EPA believes that it is inadvisable—and inconsistent with its risk assessment—to allow multiple manufacturers under the low volume exemptions.

EPA also believes that commenters have exaggerated the administrative complexities and potential for delay associated with the requirement that subsequent manufacturers of low volume substances submit a premanufacture notice. The rule establishes a system to allow companies with *bona fide* intent to manufacture a substance under a low volume exemption to determine whether their substance is already being manufactured under that exemption. EPA now operates a comparable *bona fide* system under the premanufacture notice program and finds it effective and workable. If manufacturers do not wish to face the delay associated with the *bona fide* process, they can submit an exemption notice; if another company is already manufacturing the substance under the exemption, the notice would be rejected. However, because this would happen only very rarely, it is likely that few if any manufacturers would be rejected on these grounds.

To simplify the administration of this rule, EPA will maintain a list of exempted substances and will have monthly additions to the exemption list published in the Federal Register and periodic updates in the *TSCA Chemicals-in-Process Bulletin*. As a result, prospective manufacturers of low volume substances may be able to determine whether a given substance is eligible for the low volume exemption. However, because substances will be listed under generic names when their identities are confidential, it may still be necessary for companies to make *bona fide* inquiries, or to submit exemption notices without absolute certainty that another company is not already making the substance under the exemption.

#### D. Public Notice

In the preamble to the proposal, EPA stated that exempt substances will not be added to the TSCA Chemical Substance Inventory because they have not undergone section 5 premanufacture review. As a result, the public would have no way of knowing which chemical substances were being manufactured under the exemption. This would reduce public knowledge concerning EPA's conduct of the exemption review process, and would make it difficult for chemical companies to determine if a particular chemical substance was being



manufactured under an exemption. Without a list of exempt substances, manufacturers would find it more difficult to ascertain whether a specific new chemical substance was already being manufactured under an exemption and therefore whether it was eligible for the low volume exemption.

For these reasons, EPA will maintain a list of substances that have cleared exemption review, and will publish updates to the names of the substances added to the low volume exemption list. These updates will appear monthly as notices in the *Federal Register* and appear periodically in the *TSCA Chemicals-in-Process Bulletin*. If the identity of a given chemical substance is claimed confidential, EPA will publish a generic chemical name supplied by the manufacturer, or one that it has developed as described in Unit II.B.10 of this preamble. In addition, EPA will maintain a low volume exemption public file comparable to the PMN public file. Sanitized versions of exemption notices submitted under this rule will be placed in the file. Companies are required to submit sanitized notices, with all confidential material deleted, together with any notices containing confidential business information.

Together, the published low volume exemption list and the public file will give the public a reasonable understanding of the scope of the program and the nature of the substances being manufactured under the exemption. They will also simplify procedures for companies intending to manufacture substances under the exemption.

#### IV. Regulatory Analysis

To support the August 4, 1982 proposal, EPA prepared a risk assessment and an economic analysis. After reviewing public comments, EPA revised these documents, modifying them where necessary to reflect changes in the final rule. The final documents are available in the public record of this rulemaking. The documents are summarized briefly below. This unit also explains the basis for the Agency's finding of no unreasonable risk.

##### A. Summary of Risk Assessment

###### 1. General Approach

In its analysis of the risks posed by low volume chemical substances, EPA evaluated the risks that could be associated with toxic volume substances without the various restrictions or conditions that could be included in an exemption. This analysis provided an estimate of possible risks from such substances and a basis for

determining whether or not specific safeguards would be needed. EPA then considered the impact of the exemption conditions to determine the extent to which they would reduce the risks. Although such reductions in risk were not readily quantifiable, EPA believes that the provisions of the exemption will reduce the risks estimated in the assessment so that unreasonable risks will not occur.

EPA's general approach in evaluating potential risks from low volume substances involved:

- (1) Selecting hazards (i.e., adverse health and environmental effects) that are of concern in protecting human health and the environment.
- (2) Determining a representative range of potencies for assessing each of the effects of concern.
- (3) Defining exposure scenarios.

###### 2. Low Volume Chemical Substances

a. *Analysis of potential health and environmental effects.* In analyzing low volume chemical substances, EPA selected a range of potencies for certain health effects for hazard evaluation. This procedure is justified by the fact that nothing inherent in low volume substances limits their toxicity. However, very few new low volume substances are likely to exhibit the upper ranges of toxicity represented in the risk assessment.

b. *Exposure assessment.* The exposure assessment illustrates that while low production volume in itself sets bounds on potential for exposure and environmental release, the manufacture, processing, and use of such substances can in some circumstances result in significant exposure.

i. *Occupational exposure.*—Low production volume typically limits the total number of workers who may be exposed to chemical substance, as well as the duration and frequency of exposure. However, the actual exposure levels for individual workers may be substantial. Based on PMN data, about four workers are exposed, on the average, during manufacture of chemical substances produced in quantities of 1,000 kilograms or less per year. Duration of exposure associated with manufacture averaged about 5 hours per day, and the average number of days of production per year was 62.

Only a limited number of PMNs included estimates of workplace concentration. The average concentrations associated with manufacture were most often in the ranges of 0-1 and 1-10 mg/m<sup>3</sup> for airborne solids and in the 1-10 ppm range for vapors. EPA's evaluation of Occupational Safety and Health

Administration (OSHA) data (USEPA-OTS, "Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment," March 19, 1982) indicated an average TWA concentration of 0.14 mg/m<sup>3</sup>, with a maximum value of 0.6 mg/m<sup>3</sup> for airborne solids, and an average TWA of 6 ppm, with a maximum value of 72 ppm for vapors. EPA believes that data obtained from OSHA monitoring activities provide more reliable estimates of workplace concentrations.

EPA's analysis indicated that processing and use operations may result in a higher level of exposure than manufacturing operations. Also, the average number of workers exposed during processing and use operations exceeded the average number typically exposed during manufacture. The number averaged 12 workers for a substance processed in quantities of 1,000 kilograms or less per year.

ii. *Consumer exposure.*—Consumer exposure was assessed for five use scenarios—photographic chemicals used in home darkrooms, spray adhesives, paints, dyes, and fragrances used in soaps, detergents, or shampoos. The use scenarios, which reflect actual uses reported in PMNs, were selected to represent a range of potential exposure situations.

According to EPA's analysis, the individual lifetime average daily exposures in these scenarios ranged from negligible levels for dyes in dyed fabrics to 0.0016 mg/kg/day for a fragrance in soap. Many of the scenarios could result in the exposure of relatively large numbers of consumers. At the 1,000-kg/yr production level the estimated number of consumers exposed ranges from 440,000 for a fragrance in shampoo to 26,000 for an additive in spray adhesives. Because the concentration of the substance in final products would remain constant, reduction in production volume is likely to reduce only the number of consumers exposed, not the exposure to each individual.

iii. *Environmental release.*—The exposure analysis indicated that the average quantity released to water is 0.08 percent of production volume, with an upper bound of 0.4 percent. However, some processing and industrial uses result in more substantial release rates with a range from 0.3 to 25 percent of the production volume released to water. Releases to air average 0.03 percent of production volume, with a 0.2 percent upper bound. Discharges of a new low volume substance from a single site processing 1,000 kilograms of the substance were estimated to produce



environmental concentrations ranging from <0.0005 to 0.53 ppm in a receiving stream whose stream dilution factor was equal to the national median for streams receiving effluents from industrial facilities.

In some cases, environmental releases from consumer uses equaled the total production volume. However, the actual magnitude of environmental exposure was determined to be insignificant because of the low production volume, the wide distribution of release, and the small amount of the new substance typically contained in consumer products.

c. *Estimated risks.* Given the above exposure and environmental release estimates, EPA evaluated the risks to workers, consumers, aquatic organisms, and persons living near a plant manufacturing or processing low volume chemical substances.

Although EPA expects that most low volume substances will present low risks, the assessment illustrated that workers could be subjected to significant health risks from potent or moderately potent carcinogens, teratogens, neurotoxins, or reproductive hazards. Airborne concentrations of low volume substances appear to present negligible risk to general populations, except when the released substance is a highly potent carcinogen or teratogen. Aqueous releases that may contaminate drinking water also appear to present low risks, except where the released substance is a highly potent toxic agent or where direct discharge occurs at the maximum release estimated by EPA.

Consumer exposure under most of the scenarios considered appears to present significant risks if the new substance is at least a moderately potent carcinogen. In addition, potent and moderately potent teratogens, neurotoxins, and reproductive hazards might also present substantial risks.

Environmental risks from most low volume substances would not present substantial risks to aquatic organisms at estimated discharge rates. However, EPA's analysis also demonstrates that it is reasonable to expect that a small number of substances may present substantial risks to aquatic organisms at anticipated high stream concentration levels.

d. *Chemical substances manufactured at 1,000 kilograms or less per year.* For chemical substances manufactured at 1,000 kilograms or less per year, fewer workers and consumers (than those associated with higher production volumes) are likely to be exposed. Actual exposure at this level of production will in most cases be substantially less than that indicated in

the exposure analysis, which is based in part on available data from relatively large scale operations.

For small scale operations to reach the workplace exposure indicated in the exposure assessment, production of the total 1,000 kilograms generally would have to take place in a relatively short time—perhaps as short as a day or two. In this case, the duration of exposure would be low, and therefore the potential for adverse chronic effects would be significantly reduced. Where manufacture took place over a relatively long period, workplace exposure would be unlikely to reach the levels identified in the exposure assessment (USEPA-OTS, "Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment," March 19, 1982).

Small volume operations are typically conducted over an extended period only if there is a need for careful control (for example, to ensure product purity); this control would be likely to reduce exposure. Because of the small daily production volume, the small size of equipment, and the localized nature of operations, effective control is possible, and environmental release and exposure to the worker from activities such as material transfer, sampling, and cleanup is minimized.

In addition, substances produced at 1,000 kilograms or less per year will not typically receive wide distribution. In many cases, they are produced for limited purposes or do not achieve commercial success and thus do not remain on the market long. Therefore, widespread or long term exposure to commercial users or consumers is unlikely.

### 3. Risk Under Exemption Conditions

There are several elements of the exemption that will substantially reduce the risks to human health and the environment identified in the risk assessment. The most important of these elements are the low risk associated with low volume and the 21-day EPA premanufacture review.

The basis for low risk associated with low volume is the inherent expectation of low exposure potential because of the small quantities being manufactured. Risk will be reduced by the exclusion from the exemption of chemical substances where EPA determines that they may cause serious human or environmental effects under conditions of manufacture, processing, distribution in commerce, use, and disposal.

EPA's 21-day premanufacture review for all chemical substances manufactured under this exemption will exclude from exemption those chemical

substances that fail to meet these standards, and will provide a level of protection equivalent to that now provided in the PMN program.

### B. Summary of Economic Analysis

#### 1. Introduction

To perform the economic analysis of the low volume exemption, the Agency created a data base from a sample of about 500 PMNs which represented the total submitted during a specific period in 1980 and 1981. This data base provides an overview of the Agency's experience with the PMN program. The Agency reviewed this data base to determine types of chemical substances being submitted for review, their projected production volumes, their intended uses, and in some cases their potential toxicity. This information was used to estimate the number of new substances that would be likely to be eligible for an exemption.

The Agency also reviewed the current cost of PMN requirements for manufacturers of new low volume substances; it estimated the direct relief to industry, reflected in decreased reporting costs and decreased time in bringing a new substance to the market, that would result from different exemption alternatives. It estimated direct savings to EPA resulting from decreased PMN review costs. These figures were used to derive quantitative estimates of benefits.

In assessing benefits, EPA also considered nonquantifiable benefits, such as increase in chemical innovation. Although the Agency could not attach specific figures to these benefits, they are likely to be substantial. EPA's analysis of the impact on industry of the PMN rule suggests that the nonquantifiable costs of the program may be greater than the quantifiable costs. By extension it appears reasonable to assume that the nonquantifiable benefits of an exemption may be greater than those that can be quantified.

The complete economic analysis consists of an economic support document and a supplemental memorandum and can be found in the public file.

#### 2. Current Impact of PMN Program

As a baseline for its economic analysis, EPA estimated the annual direct costs of submitting PMNs on low volume substances. A review of the sample of 500 PMNs indicates that about 21 percent of all PMNs (210 out of the annual submission rate of 1,000 PMNs) are substances produced in quantities of



1,000 kilograms or less per year. Using the current PMN reporting costs, the annual reporting costs to industry for low volume substances can be estimated to be between \$273,000 and \$1,575,000.

Besides these direct filing costs, industry is also faced with additional costs from the TSCA-imposed 90-day PMN review period (delay costs), from having to assert and possibly substantiate confidential business information claims, and from uncertainty.

### 3. Benefits of the Exemption

The Agency estimated the number of new chemical substances that would be eligible for the exemption by counting the number of chemical substances for which there are PMNs that fall under the exemption. From this number, EPA then calculated the annual net benefits of the exemption. These benefits include the actual cost savings to industry for not having to submit PMNs and the savings from the reduction of the 90-day delay. The costs of having to submit the exemption notices are subtracted from the gross savings to obtain the net savings to industry.

Assuming a rate of 1,000 PMNs a year, the low volume exemption would exempt about 210 new substances per year; net benefits to industry would be between \$460,000 and \$1,450,000 or between \$2,190 and \$6,905 per exempted chemical. The "low" end of the net benefits range was based on the lowest estimates of the cost to submit a PMN; the "high" end of the benefits was based on the highest estimates of these figures. This cost figure also includes the discounted costs of submitting a PMN in the third year for chemical substances whose production volume would exceed the volume limit by the third year of production.

The economic analysis also indicates that the exemption may lead to direct savings in EPA resources that would otherwise be spent reviewing PMNs. For low volume chemical substances, the saving would be \$19,000, or \$91 per exempted chemical. These figures reflect the difference between costs of reviewing a PMN and estimated costs of reviewing an exemption notice. Of course, EPA resources would not be freed if the availability of the exemption led to an increase in innovation and a significant increase in the overall number of submissions to EPA.

In addition to the benefits which EPA has quantified, there are certain benefits which the Agency has examined qualitatively. Chief among these are the benefits of reduced uncertainty and of increased innovation. The reduction in

the length of the review period from 90 to 21 days would reduce the period of uncertainty about the outcome of EPA's review of the notice (whether the substance would be manufactured, when, and under what restrictions, if any, etc.). Also, by reducing direct PMN filing costs and delay costs, the exemption will encourage chemical innovation. These reductions will mean that substances which formerly were not profitable to introduce would not be acceptable investments. The net value of this additional innovation would constitute additional benefits, both to the chemical industry and to society.

### C. Finding of No Unreasonable Risk

#### 1. Statutory Background

Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such substances.

The term "unreasonable risk" is not defined in TSCA. The legislative history indicates that determination of whether a risk is unreasonable requires a balancing of the probability and severity of harm from the substance or category of substances against the cost of the regulatory action to society. Because EPA's determination of the reasonableness of risk involves a consideration of factors such as environmental effects, use patterns, and market potential, which are frequently difficult to define and quantify precisely, EPA must rely not only on the available data but also its professional judgment. Congress recognized that the implementation of the unreasonable risk standard "will vary depending on the specific regulatory authority which the Administrator seeks to exercise." [Legis. Hist. at 422]

#### 2. EPA's Approach To Making the No Unreasonable Risk Finding

To determine whether the category of substances manufactured under the exemption presents an unreasonable risk, the Agency should consider not only the inherent risks presented by the overall exemption category, but also the extent to which specific exclusions or adjustments of the overall category definition have mitigated such potential risks. EPA must then analyze the effect on risk of any further conditions

imposed on the exemption. For example, manufacturers who intend to use the exemption must submit only a limited notice, which may affect the Agency's ability to identify risk. Because the effect of the exemption is to modify general PMN requirements, EPA should also compare the absolute risk posed by the same substances if the substance had been subject to the full notice submission requirements and minimum 90-day EPA review period.

Congress did not intend the section 5 review process to eliminate entirely all risk resulting from manufacture, processing, distribution in commerce, use, and disposal of new chemical substances, nor is it possible to do so. While section 5 gives EPA the opportunity to review all new chemical substances, the Agency is authorized to ban such substances or otherwise control against risks only (1) when it can show that the substances will present an unreasonable risk of injury to health or the environment (section 5(f) of TSCA), or (2) when there is insufficient information to evaluate the risks and EPA finds either that the manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk, or that the substance will be produced in substantial quantities and will be released in substantial amounts or will result in significant or substantial human exposure (section 5(e) of TSCA). To the extent that certain risks presented by members of a category of substances would not have been regulated by EPA during a full PMN review, assuming EPA's maximum exercise of its section 5 authorities, such risks could not be considered to be risks posed by an exemption rule.

There are two methods of calculating the benefits of the exemption which should be weighed in determining whether exempt substances will present an "unreasonable" risk. First, EPA can consider the benefits in a manner analogous to the way it would consider them if the Agency were evaluating a particular member of the category during an ordinary PMN review. Under this approach the evaluation would focus on the benefits of the substances to society, and the extent to which any regulation of the substances necessary to address risk concerns would reduce or eliminate such benefits. The basis for considering this type of benefits information is that Congress arguably did not intend to exempt from premanufacture notice requirements any substances which were likely to have been subject to control under section 5(e) or 5(f). EPA thus would not consider



the reduced burden of the PMN or other benefits of reducing PMN requirements, because these costs would not be considered in making a regulatory decision on a PMN substance. One problem with focusing on the benefits of the substances in the category is that, while section 5(h)(4) contemplates granting exemptions by category, it is difficult or impossible to predict accurately the nature of those benefits.

Under the second approach, EPA could consider benefits beyond those considered in an actual PMN review. As discussed in the proposed rule, a broader consideration of benefits would analyze, in addition to the benefits of the substances themselves, the reduction in the costs to society imposed by the full PMN requirements. There are strong arguments for taking such an approach in making a no unreasonable risk finding in the context of a section 5(h)(4) exemption. The legislative history indicates that EPA's unreasonable risk consideration should include effects on society beyond the benefits of a substance. In addition, unlike the review of an individual PMN, the costs of PMNs for substances which would be addressed by this exemption have not already been paid. Such direct costs would include the cost of preparing and submitting the PMN, and the cost of the delay in the introduction of the benefits of a new chemical. In addition, economic analyses have indicated that reporting and delay costs may discourage the introduction of new chemical substances. While elimination of these costs would not be a benefit that EPA would take into account in making an individual control decision on a new substance, they are real effects on society which result from EPA's exercise of its exemption authority and are thus appropriately considered in a section 5(h)(4) unreasonable risk finding for a category of substances.

### 3. Exemption Conditions

There are several exemption provisions that directly or indirectly reduce the likelihood that exemption substances would adversely affect health or the environment. EPA believes that these provisions together will significantly limit risk and will adequately support a finding of no unreasonable risk, given the bounds on exposure associated with the exemption category and the benefits of the exemption.

The major provisions that limit risk are discussed below:

a. *Production volume limitation.* A critical element of the finding is that low volume chemical substances manufactured in volumes of 1,000

kilograms or less per year have limits on exposure potential. The number of workers exposed and the duration and frequency of exposure is generally limited. Uses would be for the most part limited to specialty applications, and consumer exposure would not typically occur. Under some circumstances, significant numbers of consumers could be exposed, but the levels of exposure would usually be low.

b. *EPA review.* EPA's abbreviated review plays an important role in the exemption and in the finding of no unreasonable risk. In the final rule, EPA has strengthened this review by lengthening it from 14 to 21 days. During this period, the Agency will have sufficient time to identify any problems that were likely to have been identified in a full PMN review. If EPA determines that a new chemical substance is not eligible for an exemption, manufacture cannot begin. The manufacturer is then required to comply with TSCA section 5(a)(1) before the substance can be manufactured for commercial purposes.

c. *New information and EPA revocation.* In addition to these safeguards, the rule contains several other provisions that will further limit the possibility that exemption substances will present significant risks. Most important, the rule establishes procedures for revocation of the exemption if EPA later determines that the substance does not meet the conditions of the exemption. In addition, EPA has the authority to require documents relevant to an exemption from the manufacturer (in addition to the information provided in the exemption notice), and the manufacturer is required to submit promptly to EPA any new data indicating that a substance is ineligible. These provisions will ensure that eligibility for the exemption will be determined on the basis of the best available information, regardless of when the information becomes available.

### 4. Benefits

It is impossible to quantify the total benefits which may accrue to society from the individual substances subject to this exemption. Uncertainty about benefits is inherent in any action under TSCA which deals with a category of substances whose structure and uses are unknown. However, it is clear that the field of chemistry has been the source of many recent technological advances, particularly in the area of low volume specialty chemicals. In addition, it is obvious that a new chemical substance must present benefits to society by performing a new function, or performing an old function more

efficiently or less expensively, or with less risk, or it would not have been developed or used. Therefore, EPA has concluded that the new chemical substances eligible for exemption, as a category and as individual substances, will present some significant benefits to society.

EPA was able to quantify some of the benefits to society which will result from this exemption that do not depend on specific knowledge about the benefits of the individual substances. First, as is indicated above, manufacturers submitting notices under this exemption will incur reduced reporting costs. Second, there will be a potential for significant reduction in the delay in introducing new substances. Manufacturers, and the general public, will be able to take advantage of the benefits of individual new low volume substances more quickly, including any increases in efficiency and decreases in cost.

Assuming that approximately 210 new chemical substances a year would be manufactured under the exemption, net benefits would be between \$46,000 and \$1,450,000 annually. Of this amount, a significant portion consists of the savings in costs due to reduced delay. Total industry costs associated with the PMN program are presently estimated at \$3.715 to \$9.915 million annually. The final exemption rule will therefore reduce this cost to industry by about 12 to 15 percent.

### 5. Conclusion

Given the limitations on risk posed by substances manufactured under this exemption and the benefits that would be derived from them, EPA has determined that substances manufactured under the terms of this exemption rule will not present an unreasonable risk.

### V. Judicial Review

To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review 2 weeks after publication in the *Federal Register*, as reflected in "DATES" in this notice. The effective date has, in turn, been calculated from the promulgation date.

### VI. Record

EPA has established a record for this rulemaking (Docket Number: OPTS-50032) which is available for inspection in Rm. E-107, 401 M St. SW., Washington, D.C. 20460. Persons who do not have access to the record in the



public reading room should contact Edward A. Klein, Director, TSCA Assistance Office (TS-799), at the above address for assistance.

The record includes all information considered by the Agency in developing this exemption proposal. The preamble to the proposal lists items entered into the record through June 1982. The list below identifies items entered into the record after that date. These lists together identify the complete rulemaking record:

57. Adhesives Manufacturers Association. "Letter Endorsing the Chemical Manufacturers Association Petition for PMN Exemptions," August 13, 1981.

58. USEPA-OTS. "Letter from Edward A. Klein, Director, Chemical Control Division, to Bill Ahrens, Adhesives Manufacturers Association," September 14, 1981.

59. USEPA-OTS. "Premanufacture Notification: Proposed Exemption for Site-Limited Intermediate Chemical Substances Manufactured in Quantities of 10,000 Kg or Less Per Year," 47 FR 33896, August 4, 1982.

60. Comments received in response to proposed rule exempting certain new site-limited intermediates and low volume chemicals from premanufacture notice requirements, 47 FR 33896 (52 comments).

61. USEPA-OTS. "OTS-DETO Meeting Summary," Summary of meeting with Dyes Environmental and Toxicology Organization (DETO), September 14, 1982.

62. USEPA-OTS. "Summary of Meeting with Brulin and Co., Inc.," October 4, 1982.

63. Transcript of public meeting on proposed rule exempting certain site-limited intermediates and low volume chemicals from premanufacture notice requirements, 47 FR 33896 (6 exhibits).

64. USEPA-OTS. "Questions for Participants in the Public Hearing," November 1, 1982.

65. Comments received in response to public hearing on proposed exemption for site-limited intermediates and low volume chemical substances (7 comments).

66. Chemical Manufacturers Association (CMA). "Supplemental Comments on Proposed Exemption Rule under section 5 (b)(4) of the Toxic Substances Control Act," March 21, 1983.

67. CMA. "Letter to Don R. Clay, Acting Assistant Administrator for Pesticides and Toxic Substances," June 2, 1983.

68. USEPA-OTS. "Response to Comments on Proposed PMN Exemption for Low Volume Chemicals," December 31, 1984.

69. Office of Management and Budget (OMB). "PMN Exemption Rules: Staff Option," November 7, 1983.

70. SOCMA. "Letter to William Ruckelshaus, Administrator of the Environmental Protection Agency," January 23, 1984.

71. USEPA-OTS. "Economic Impact Analysis of TSCA Section 5(h)(4) Exemptions: Low Volume and Site-Limited Intermediate Chemicals," September 1983.

72. USEPA-OTS. "Memorandum: Economic Analysis of the Final Exemption Rule for Low Volume Chemicals," Revising "Economic

Impact Analysis of TSCA Section 5(h)(4) Exemptions, Low Volume and Site-Limited Intermediate Chemicals," October 26, 1984.

73. USEPA-OTS. "Risk Analysis in Support of the Proposed Exemption of Site-Limited Intermediates and Low Volume Chemicals," December 5, 1983.

74. USEPA-OTS. "Health and Environmental Risk Assessment of TSCA Section 5(h)(4) Exemption for New Low Volume Chemicals," revising "Risk Analysis in Support of the Proposed Exemption of Site-Limited Intermediate and Low Volume Chemicals," November 1, 1984.

75. USEPA-OTS. "Low Volume Exemption—Occupational Exposure and Environmental Release Assessment," March 1982.

76. USEPA-OTS. Memorandum "Engineering Assessment of the Final Exemption Rule for Low Volume Chemicals," October 30, 1984.

## VII. Application of Executive Order 12291, Paperwork Reduction Act, and Regulatory Flexibility Act

This regulation does not satisfy any of the criteria for major regulation described in Executive Order 12291; therefore, EPA has determined that a Regulatory Impact Analysis is not necessary. The annual impact of the rule on the economy will not exceed \$100 million; instead it will provide substantial relief to the regulated industry. The rule will not burden any particular geographic region and will not affect government agencies, except that it may reduce the burden of PMN review for EPA. The exemption will not adversely affect the ability of domestic manufacturers to compete with foreign manufacturers or vice versa and it will encourage chemical innovation. EPA expects that the net effect of this exemption rule on the economy will be positive.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small businesses. Instead, it will provide relief from the burdens of the present PMN requirements, and is likely to be particularly beneficial to small businesses. The Chemical Specialties Manufacturers Association, which represents many small businesses, has stated that "declines in the rates of projected innovation as a result of TSCA costs were on the whole substantial, and were particularly heavy for firms in smaller size classes." Since the exemption will reduce PMN filing costs and shorten production delays,

small manufacturers will especially benefit from the rule.

In addition, small firms will benefit because they submit a disproportionately large percentage of PMNs on low volume chemical substances. According to the PMN data base, 31 percent of the PMN submissions by small firms have been on substances with projected production volumes of 1,000 kilograms or less per year, while only 21 percent of all PMNs have been on such substances. Therefore, the low volume exemption is likely to provide proportionately greater relief to these small firms. For this reason, the Agency has not prepared a Regulatory Flexibility Analysis for this rule.

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070-0012.

## List of Subjects in 40 CFR Part 723

Chemicals, Environmental protection, Premanufacture notification exemption, Hazardous substances, Recordkeeping and reporting.

Dated: April 19, 1985.

Lee M. Thomas,  
Administrator.

## PART 723—[AMENDED]

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended by adding a new § 723.50, to read as follows:

### § 723.50 Chemical substances manufactured in quantities of 1,000 kilograms or less per year.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain chemical substances manufactured in quantities of 1,000 kilograms or less per year.

(2) To manufacture a new chemical substance under the terms of this exemption, (i) a manufacturer must submit a notice of intent to manufacture 21 days before manufacture begins, as required under paragraph (e) of this section; and (ii) the manufacturer must comply with all other provisions of this section.

(b) *Definitions.* (1) "Act" means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).



(2) The terms "article," "byproduct," "EPA," "health and safety study," "importer," "impurity," "known to or reasonably ascertainable,"

"manufacture," "new chemical substance," "person," "possession or control," "test data" have the same meanings as in § 720.3 of this chapter.

(3) The term "Assistant Administrator" means the EPA Assistant Administrator for Pesticides and Toxic Substances or any employee designated by the Assistant Administrator to carry out the Assistant Administrator's functions under this section.

(4) The term "category of chemical substances" has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625(c)(2)).

(5) "Director of the Office of Toxic Substances" means the Director of the EPA Office of Toxic Substances or any EPA employee designated by the Director to carry out the Director's functions under this section.

(6) The term "environment" has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(7) "Environmental transformation product" means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(8) "Metabolite" means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(9) "Serious acute effects" means human disease processes or other adverse effects that have a short latency period for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(10) "Serious chronic effects" means human disease processes or other adverse effects that have a long latency period for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(11) "Significant environmental effects" means either:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society,

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year, or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. "Endangered" or "threatened" species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(12) "Site" means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site.

(c) *Exemption categories.* Any person who intends to manufacture (including import) a new chemical substance in quantities of 1,000 kilograms or less per year may seek an exemption under this section for that chemical substance, subject to the conditions specified in paragraph (d) of this section. No more than one person may hold an exemption for a particular new chemical substance under this paragraph.

(d) *Exclusions—(1) Chronic effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the substance or a reasonably anticipated metabolite or environmental transformation product of it may cause serious chronic effects, including carcinogenic and teratogenic effects, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(2) *Acute effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the substance or a reasonably anticipated metabolite or environmental transformation product of it may cause serious acute effects (lethal or sublethal) under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(3) *Environmental effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the new chemical substance or a reasonably anticipated environmental transformation product of it may cause significant environmental effects under

anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(4) *Impurities.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that reasonably anticipated impurities in the substance may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(4) *Impurities.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that reasonably anticipated impurities in the substances may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(5) *Byproducts.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the reasonably anticipated byproducts of manufacture, processing, distribution in commerce, use, or disposal of the substance, including waste or emissions, may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(e) *Exemption notice.* (1) The manufacturer must submit a notice to the Document Control Officer as provided in paragraph (n) of this section at least 21 days before manufacture begins. The date of submission will be the date on which the notice is received by the Document Control Officer. EPA will acknowledge the receipt of the notice by letter. The letter will identify the date on which the review period begins. The notice must include:

(i) *Manufacturer's name.* The name and address of the manufacturer of the new chemical substance and the name and telephone number of a technical contact must be provided.

(ii) *Type of exemption.* The exemption notice must indicate that the manufacturer is seeking a low volume exemption.

(iii) *Chemical identification—(A) Class 1 substances* (chemical substances whose composition can be represented by a definite structural



diagram). The chemical name (preferably Chemical Abstract Services (CAS) or International Union of Pure and Applied Chemistry (IUPAC) nomenclature), the molecular formula, CAS Registry Number (if available), and a structural diagram.

(B) *Class 2 substances* (chemical substances that cannot be fully represented by a structural diagram). The chemical name, the molecular formula, the CAS Registry Number (if available). The notice must identify the immediate precursors and reactants by name CAS Registry Number (if possible). The notice must include a partial or incomplete structural diagram (if available). Chemical names for such substances should be developed according to the guidelines in the TSCA Chemical Substance Inventory, Initial Inventory, Volume 1.

(C) *Polymers*. Monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number (if available); typical percent of each monomer and other reactants used in the polymer (by weight percent of total polymer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram (if possible). The notice must provide estimates of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight and describe how the estimates were obtained. This information must be provided to the extent it is known or reasonably ascertainable by the submitter.

(D) *Impurities*. Impurities anticipated to be present in the new chemical substance by name, CAS Registry Number (if known), and weight percent of the total substance. If there are unidentified impurities, the notice must include an estimate of their total weight percent. Information on impurities must be provided to the extent that it is known to or reasonably ascertainable by the submitter.

(E) *Generic name*. If the manufacturer claims the chemical identity of the new chemical substance confidential, he or she must submit a generic name in accordance with paragraph (k)(2) of this section. The name should be only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. It should reveal the specific chemical identity to the maximum extent possible.

(iv) *Description of use*. Each use for which the chemical substance would be manufactured by function and application (e.g., spray adhesive in the manufacture of laminates). The

description of use must indicate whether the use is industrial, commercial, or consumer.

(v) *Site of manufacture* (except for chemical substances that are imported). The notice must state the name and address of the site or sites of manufacture of the new chemical substance.

(vi) *Certification*. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(vii) *Test data*. The manufacturer must submit all test data in its possession or control which are related to the effects of the new chemical substance on health or the environment.

(viii) *Exposure controls*. The manufacturer may also provide information on exposure controls or other controls for the new chemical substance. Where a manufacturer provides such information to support the exemption notice, the manufacturer must maintain those controls throughout the period of the exemption.

(ix) *Sanitized copy of notice*. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (k) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (k)(3) of this section.

(B) If the submitter does not provide the second copy, the submission is incomplete.

(2) *Incomplete notices*. If EPA receives a submission which does not include all of the information required under paragraph (e) of this section, the submission will be determined to be incomplete by the Director of the Office of Toxic Substances. The exemption review period will not begin until EPA receives all required information.

(f) *Review period*. EPA will review the notice submitted under paragraph (e) of this section to determine whether the new chemical substance is eligible for the exemption. The review period will end 21 days after receipt of the notice by EPA. Upon expiration of the 21-day review period, if EPA has taken no action, the manufacturer may begin to manufacture the new chemical

substance under the other terms of this exemption.

(g) *Notice of ineligibility*—(1) *During the review period*. If the Assistant Administrator for Pesticides and Toxic Substances determines during the review period that the new chemical substance does not meet the terms of this section, or that there are issues concerning toxicity or exposure that require further review, the Assistant Administrator will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the issues and explains why they are unresolved. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act.

(2) *After the review period*. (i)(A) If at any time after the end of the review period specified in paragraph (f) of this section, the Assistant Administrator for Pesticides and Toxic Substances makes a preliminary determination that the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of this section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the new chemical substance after receiving notice under paragraph (g)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (g)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of notification may not begin manufacture until EPA makes its final determination under paragraph (g)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (g)(2)(i) of this section may submit detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section within 15 days of receipt of written notification.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (g)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of



the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 24 hours of the telephone notification under paragraph (g)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, or use until it submits a notice under section 5(a)(1) of the Act and Part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (g)(2)(i) of this section, and

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and Part 720 of this chapter within 15 days of receipt of the telephone notification under paragraph (g)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, and 17 of the Act.

(h) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify for the exemption, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information.

(i) *Changes in site or use.* (1) Chemical

substances manufactured under this section must be manufactured at the site or sites described and for the uses described in the exemption notice submitted in accordance with paragraph (e) of this section.

(2)(i) Any person who manufactures a new chemical substance described in paragraph (c) of this section must comply with the provisions of this section before manufacturing the new chemical substance at a site that was not reported in a previous exemption notice, including submission of a new notice under paragraph (e) of this section.

(ii) Any person who manufactures a new chemical substance described in paragraph (c) of this section must comply with the provisions of this section before manufacturing the new chemical substance for a use that was not reported in a previous exemption notice, including submission of a new notice under paragraph (e) of this section.

(3) In an exemption notice informing EPA of a change in site or use, the manufacturer is not required to provide information submitted to EPA in a previous exemption notice on that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and the new site or use. The notice must also include a certification by the manufacturer, as described in paragraph (e)(1)(vi) of this section.

(j) *Customer notification.* (1) Manufacturers of a new chemical substance described in paragraph (c) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) If the manufacturer learns that a customer is processing or using the exempt substance in violation of use restrictions or without imposing prescribed controls, the manufacturer must cease distribution of the substance to the customer immediately. The manufacturer must also report this action to EPA within 15 days under paragraph (h) of this section.

(k) *Confidentiality.* (1) If the manufacturer submits to EPA under this

section information which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in Part 2 of this Title. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the submitter will be subject to EPA review and approval in accordance with the procedures specified in § 720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(l) *Determination of first manufacturer of a new chemical substance.* (1) A person who intends to manufacture a new chemical substance under this section may determine whether that particular substance is already being manufactured under that section and, therefore, whether the person is eligible for the exemption, by submitting a notice on the substance under paragraph (e) of this section. EPA will inform the manufacturer within the 21-day review period if the manufacturer is not eligible for the exemption because another person is already manufacturing the substance under the exemption.

(2) Alternatively, the manufacturer may ask EPA whether another manufacturer is already producing the new chemical substance under this section. EPA will respond to this inquiry only if EPA determines that the manufacturer making the inquiry has shown a *bona fide* intent to manufacture the substance under the terms of this section.



(i) To establish a *bona fide* intent to manufacture a substance under this section, the manufacturer must submit to EPA:

(A) The specific chemical identity of the substance that the person intends to manufacture.

(B) A signed statement that the person intends to manufacture that chemical substance under the terms of this section.

(C) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture the chemical substance.

(D) An elemental analysis.

(E) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(ii) If an importer cannot provide all the information required by paragraph (1)(2)(i) of this section because it is claimed confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(iii) The Director of the Office of Toxic Substances will promptly examine the manufacturer's submission.

(A) If the Director determines that the manufacturer has not shown a *bona fide* intent to manufacture the new substance under the terms of this section, the Director will promptly notify the manufacturer. The manufacturer may then submit a notice under paragraph (e) of this section or a notice under section 5(a)(1) of the Act.

(B) If the Director determines that the manufacturer has shown a *bona fide* intent to manufacture the new chemical substance under the terms of this section, the Director will promptly inform the manufacturer whether the substance is being manufactured under this section. If the substance is not being manufactured under this section, the manufacturer may submit a notice under paragraph (e) of this section. If the new chemical substance is being manufactured under this section, the manufacturer must submit a notice under section 5(a)(1) of the Act.

(m) *Volume limitation.* A person manufacturing a new chemical substance under this section may not manufacture more than 1,000 kg of the substance during each 12-month period following the date the review period described in paragraph (f) of this section expires.

(n) *Submission of information.*

Information submitted to EPA under this section must be sent in writing to: Document Control Officer (TS-793),

Office of Toxic Substances, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, D.C. 20460.

(o) *Recordkeeping.* (1) Each manufacturer of a new chemical substance described in paragraph (c) of this section must maintain records of (i) the annual production volume of the new chemical substance under the exemption, and (ii) documentation of information in the exemption notice and compliance with the terms of this section. Records maintained under this paragraph must be retained for 5 years after date of their preparation.

(2) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA permit such person at all reasonable times to have access to and to copy records kept under paragraph (o)(1) of this section.

(3) The manufacturer must submit the records listed in paragraph (o)(1) of this section to EPA upon written request by the Director of the Office of Toxic Substances. Manufacturers must provide these records within 15 working days of receipt of this request.

(p) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(Approved by the Office of Management and Budget under control number 2070-0012)

(Sec. 5, Pub. L. 94-496, 90 Stat. 2012 (15 U.S.C. 2604))

[FR Doc. 85-10145 Filed 4-25-85; 8:45am]

BILLING CODE 6560-50-M

## FEDERAL EMERGENCY MANAGEMENT AGENCY

### 44 CFR Part 64

[Docket No. FEMA 6655]

### Suspension of Community Eligibility Under the National Flood Insurance Program; New York et al.

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

**SUMMARY:** This rule lists communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the flood plain management requirements of the program. If FEMA receives documentation that the community has adopted the required flood plain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the Federal Register.

**EFFECTIVE DATES:** The third date ("Susp.") listed in the fourth column.

**FOR FURTHER INFORMATION CONTACT:** Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, (202) 646-2717, 500 C Street, Southwest, FEMA—Room 509, Washington, D.C. 20472.

**SUPPLEMENTARY INFORMATION:** The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (44 CFR Part 59 et. seq.). Accordingly, the communities are suspended on the effective date in the fourth column, so that as of that date flood insurance is no longer available in the community. However, those communities which, prior to the suspension date, adopt and



submit documentation of legally enforceable flood plain management measures required by the program, will continue their eligibility for the sale of insurance. Where adequate documentation is received by FEMA, a notice withdrawing the suspension will be published in the **Federal Register**.

In addition, the Director of Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the fifth column of the table. No direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood prone areas. (Section 202(a)

of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Director finds that notice and public procedure under 5 U.S.C. 533(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified. Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required flood plain management measures are met prior to the effective suspension date. For the same reasons, this final rule may take effect within less than 30 days.

Pursuant to the provision of 5 U.S.C. 605(b), the Administrator, Federal Insurance Administration, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a

substantial number of small entities. As stated in Section 2 of the Flood Disaster Protection Act of 1973, the establishment of local flood plain management together with the availability of flood insurance decreases the economic impact of future flood losses to both the particular community and the nation as a whole. This rule in and of itself does not have a significant economic impact. Any economic impact results from the community's decision not to (adopt) (enforce) adequate flood plain management, thus placing itself in noncompliance of the Federal standards required for community participation. In each entry, a complete chronology of effective dates appears for each listed community.

#### List of Subjects in 44 CFR Part 64

Flood insurance, Flood plains.

#### PART 64—[AMENDED]

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

#### § 64.6 List of eligible communities.

State and county	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Special flood hazard area identified	Date certain Federal assistance no longer available in special flood hazard areas
<b>MINIMALS</b>					
<b>Region II</b>					
New York:					
Oneida	Augusta, town of	360517B	June 9, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Sept. 13, 1974 and Apr. 9, 1976	May 1, 1985.
St. Lawrence	Fine, town of	361177D	July 23, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 10, 1975 and Jan. 28, 1983	Do.
Saratoga	Galway, town of	360716B	July 16, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	June 14, 1974, Dec. 26, 1975, Aug. 13, 1976, and Nov. 19, 1976	Do.
Madison	Hamilton, town of	360401B	July 2, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	May 31, 1974 and May 21, 1976	Do.
St. Lawrence	Oswegatchie, town of	360706C	Aug. 27, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Sept. 13, 1974, May 26, 1976, and Apr. 4, 1984	Do.
<b>Region III</b>					
Maryland: Wicomico	Willards, town of	240082B	May 28, 1982, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 21, 1977	Do.
Pennsylvania:					
Cambria	Ashville, borough of	422266A	July 25, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Nov. 15, 1974	Do.
Butler	Brun, borough of	420211A	Mar. 7, 1977, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	July 30, 1976	Do.
Do	Cherry, township of	422342B	Mar. 7, 1977, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 10, 1975 and Jan. 16, 1981	Do.
Washington	Deemston, borough of	422132B	Nov. 20, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Nov. 1, 1974 and Oct. 24, 1975	Do.
Armstrong	Madison, township of	421308A	Sept. 27, 1976, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Nov. 22, 1974	Do.
Do	Rural Valley, borough of	422302A	Mar. 7, 1977, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 24, 1975	Do.
Butler	Verango, township of	422359A	June 3, 1977, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 24, 1975	Do.
Armstrong	Worthington, borough of	422306B	Feb. 16, 1977, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Dec. 27, 1974	Do.
West Virginia: Jackson	Unincorporated areas	540063B	Nov. 25, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 17, 1975 and Oct. 23, 1981	Do.
<b>Region II</b>					
New York:					
Oneida	Clinton, village of	360525B	Nov. 7, 1974, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Feb. 15, 1974 and May 26, 1976	May 1, 1985.
Ulster	Kingston, city of	360858C	Apr. 26, 1974, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	May 17, 1974, Jan. 18, 1980, and Nov. 26, 1975	Do.



State and county	Location	Community No.	Effective dates of authorization/renunciation of sale of flood insurance in community	Special flood hazard area identified	Date certain Federal assistance no longer available in special flood hazard areas
<b>Region III</b>					
Pennsylvania: Allegheny	Boil Acres, borough of	420008B	June 12, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	June 7, 1974 and Apr. 23, 1976	Do
<b>Region V</b>					
Ohio: Hamilton	Village of Indian Hill, city of	390221B	July 18, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	June 28, 1974 and June 4, 1976	Do
<b>Region VI</b>					
Louisiana:					
Plaquemines Parish	Unincorporated areas	220139B	June 20, 1973, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Jan. 17, 1985	Do
St. Bernard Parish	do.	225204B	Mar. 12, 1970, Emerg.; Mar. 13, 1970, Reg.; May 1, 1985, Susp.	Mar. 13, 1970, July 1, 1974, and Feb. 6, 1975	Do
Terrebonne Parish	do.	225206C	July 17, 1970, Emerg.; Nov. 20, 1970, Reg.; May 1, 1985, Susp.	Nov. 20, 1970, July 1, 1974, Nov. 19, 1976, and Dec. 16, 1980	Do
<b>Region IX</b>					
California:					
Kern	Bakersfield, city of	060077B	Aug. 7, 1975, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Aug. 16, 1974 and Aug. 6, 1976	Do
Riverside	Calhestral City, city of	060704	Nov. 12, 1982, Emerg.; Nov. 12, 1982, Reg.; May 1, 1985, Susp.	May 1, 1985	Do
Contra Costa	Walnut Creek, city of	065070B	Jan. 29, 1971, Emerg.; May 1, 1985, Reg.; May 1, 1985, Susp.	Nov. 6, 1974 and Oct. 8, 1976	Do

Code for reading 4th column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001-4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Administrator, Federal Insurance Administration)

Issued: April 22, 1985.

Jeffrey S. Bragg,

Administrator, Federal Insurance Administration.

[FR Doc. 85-10093 Filed 4-25-85; 8:45 am]

BILLING CODE 6718-03-M

#### 44 CFR Parts 80, 82, and 83

##### Crime Insurance Program

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Final rule.

**SUMMARY:** These revisions to the Federal Crime Insurance Program achieve the following: They raise the premiums for commercial crime insurance policies, revise the number of premium classes by which applications for crime insurance are rated and amend the protective device requirements for some commercial business to permit a premium modification for specific degrees of protection. The regulations also provide more detailed and helpful instructions for calculating premiums and identifying the classification of businesses.

On January 29, 1985, the Federal Insurance Administration, Federal Emergency Management Agency, published for comment in the Federal

Register a proposed rule containing these revisions which were based on a study performed by the Federal Insurance Administration and the Actuarial Firm of Tillinghast, Nelson and Warren, Inc. comparing the premiums of the Federal Crime Insurance Program to the Insurance Service Office advisory premiums used by the private sector.

**DATE:** This rule will be effective for commercial crime insurance business written after May 1, 1985, and renewal policies not already billed to existing policyholders.

**FOR FURTHER INFORMATION CONTACT:** Robert J. DeHenzel, Federal Emergency Management Agency, Federal Insurance Administration, Donohoe Building, 500 C Street, SW., Room 433, Washington, DC 20472, telephone number (202) 646-3440.

**SUPPLEMENTARY INFORMATION:** All written comments received during the comment period were duly considered prior to publication of the final rule. These revisions are the result of the experience gained in the thirteen (13) years the Federal Crime Insurance Program has been in operation and are the direct result of the affordability study conducted by the Federal Insurance Administration and the Actuarial Firm of Tillinghast, Nelson and Warren, Inc. during the past two years. While the base premium level for commercial policies is subject to an overall increase of 35%, the ultimate revenue collected under the plan is, in addition, affected by the protective device requirements and package credit plan. Installation of additional

protective devices will serve to lower the burglary premium for insureds who thereby reduce their exposure to crime losses. The package plan will provide a 10% discount to any insured purchasing both burglary and robbery. Thus, despite the fact that the Federal Insurance Administration is increasing the base premiums for commercial policies by 35%, the premiums continue to be affordable and the revenue change under the plan is only +13.2%.

FEMA has determined that an environmental impact statement is not needed for this rule. A copy of the finding of no significant impact and an environmental assessment is available at the above address.

##### List of Subjects

44 CFR Parts 80 and 83

Crime insurance.

44 CFR Part 82

Crime insurance, Security measures.

Accordingly, 44 CFR Parts 80, 82, 83 are amended as follows:

#### PART 80—DESCRIPTION OF PROGRAM AND OFFER TO AGENTS

##### § 80.1 [Amended]

1. Section 80.1 is amended by redesignating paragraphs (a)(6)–(a)(14) as (a)(7)–(a)(15) respectively.

2. Section 80.1 entitled Definitions paragraph (a) is amended by adding new paragraph 6 entitled discounts to read as follows:



**§ 80.1 Definition.**

(6) "Discounts": The premium credit issued to businesses protected by a burglar alarm system, considered adequate for the type of risk involved.

**PART 82—PROTECTIVE DEVICE REQUIREMENTS****Subpart A—General**

1. Section 82.1 is amended by redesignating paragraphs (c)–(j) as paragraphs (d)–(k).

2. Section 82.1 entitled "Definitions" is further amended by adding new paragraph (c) "Central Station, Supervised Alarm System (without guard dispatch)" to read:

**§ 82.1 Definitions.**

(c) "Central Station, Supervised Alarm System (without guard dispatch)" means a silent alarm system that is constantly in operation, which signals upon any breach of a door, windows (including store front windows and unbarred skylights), or other accessible openings to the protected premises, at an office of the law enforcement authorities or at an office of an independent agency, located at a distance from the protected property, which has trained operators continually on duty twenty four (24) hours a day to receive signals and to notify law enforcement authorities as soon as any breach of the premises is confirmed.

3. Section 82.5 entitled "Inspection of commercial premises" is amended by revising the existing paragraphs (b) and (d) to read as follows:

**§ 82.5 Inspection of commercial premises.**

(b) Coverage under a commercial crime insurance policy indemnifying against burglary losses shall not commence unless it is determined that the premises sought to be insured comply with all applicable protective device requirements. Provided, That all commercial premises whose exterior doors and accessible openings are found upon inspection to be protected by central station supervised service alarm systems or silent alarm systems (as those systems are defined in paragraphs (b), (c), and (l) of § 82.1) shall not be required to comply with the provisions of paragraphs (b) and (e) of § 82.31 pertaining to the protection of those exterior doors and accessible openings by such devices as bars, grillwork, and

other physical barriers. The benefit of this provision, therefore, applies also to commercial premises which, because of their particularly high risk inventories of merchandise continue to be required by paragraphs (f) (1) and (2) of § 82.31 to have exterior doors and accessible openings protected by specified types of alarm systems, namely, supervised service alarm systems for the highest risk inventories and silent alarm systems for less high risk inventories.

(d) Because the statement of annual gross receipts is a significant factor in the determination of the correct premium, the annual gross receipts figures (ventas netas for Puerto Rico) or the Total Income of the tax returned as derived from interest, rents, capital gains, etc., reported on the application or at the time of renewal shall be verified at the time of the adjustment of any loss. The applicant or insured shall at the time make available any necessary documentation to substantiate the annual gross receipts figure reported.

(e) \* \* \* The Administrator may also in his or her discretion determine that the frequency and/or severity of occurrences of loss experienced under any policy issued under the provision of paragraphs (b) and (c) of this section, requires that as a condition of continuation of coverage on renewal of such policy the premises insured thereunder be protected by one or more of the protective devices described in paragraphs (a), (b), (c), (d), (e), (f) (1), (2), (3), and (4) of § 82.31 for applicable points of entry for incurred losses.

4. Section 82.31 entitled "Minimum standards of industrial and commercial properties" paragraph (f) is revised as follows:

**§ 82.31 Minimum standards for industrial and commercial properties.**

(f) The following types of establishments whose inventories pose a particularly serious risk shall, as a minimum, in addition to the requirements of paragraphs (a), (b), and (d) of this section be protected by the type of alarm system indicated. If the system specified in paragraphs (f)(1) and (f)(2) of this section is not available in the community in which the premises are located, the type of system specified in paragraph (f)(3) of this section shall be permitted. In addition to, but not in place of, any central station supervised alarm system or silent alarm system required under paragraphs (f) (1), (2) and (3) of this section, an insured may also utilize a local alarm system.

(1) Central Station (with Guard dispatch) supervised service alarm system shall be required for the following businesses:

- (i) Beer/Wine—Wholesale.
- (ii) Boutiques.
- (iii) Cameras/Photo Supplies/Film Processing—Wholesale/Retail/Mfg.
- (iv) Clothing/Men's (age 12 and over)—Wholesale/Retail.
- (v) Clothing/Women's (age 12 and over)—Wholesale/Retail.
- (vi) Drug Stores and Druggists Sundries.
- (vii) Electrical Appliances/Apparatus/Parts—Wholesale/Retail/Mfg.
- (viii) Food Stuffs/Wholesale.
- (ix) Gasoline Service Station/Fuel Dealers.
- (x) Jewelry—Retail/Wholesale/Mfg./Storage.
- (xi) Liquor Sales—Retail.
- (xii) Pawnbrokers.
- (xiii) Precious Metals/Electroplating—Mfg./Wholesale/Retail.
- (xiv) Radio/TV/Stereo/Electronic Equipment/Computer—Wholesale/Retail/Mfg.
- (xv) Record Shop.
- (xvi) Tobacco—Wholesale.
- (xvii) Used Clothing/Shoe Repair/Thrift Shops.
- (xviii) Variety Stores/Department Stores.

(2) Central Station (without Guard dispatch) supervised service alarm system shall be required for the following businesses:

- (i) Art Supplies—Retail/Wholesale/Mfg.
- (ii) Auto Parts—(No Service)—Wholesale/Retail/Mfg.
- (iii) Beer/Wine with Food Retail.
- (iv) Drugs—Wholesale.
- (v) Dry Goods/Textiles/Sewing Material—Wholesale/Retail/Mfg.
- (vi) Furniture/Home Furnishing/ Floor Covering/Upholstery—Wholesale/Retail/Mfg.
- (vii) Furriers—Wholesale/Retail/Mfg./Storage.
- (viii) Grocery Stores/Delicatessens/Health Food Stores.
- (ix) Guns/Ammunition—Wholesale/Retail/Mfg.
- (x) Hardware/Houseware—Wholesale/Retail/Mfg.
- (xi) Hobby Shops/Toys/Novelty—Wholesale/Retail/Mfg.
- (xii) Leather Products—Wholesale/Retail/Mfg.
- (xiii) Liquor—Wholesale.
- (xiv) Meat/Poultry/Fish Dealers.
- (xv) Music Stores/Instruments/Supplies—Wholesale/Retail/Mfg.
- (xvi) Precious Metals/Electroplating—Wholesale/Retail/Mfg.



(xvii) Shoe Stores—Wholesale/Retail/Mfg.  
 (xviii) Sport Goods—(General)—Wholesale/Retail/Mfg.  
 (xix) Tobacco Dealers—Retail.  
 (xx) Wig Shops.  
 (3) Silent alarm system shall be required for the following businesses:  
 (i) All Risks Not Otherwise Classified.  
 (ii) Amusement Enterprises.  
 (iii) Antique Store.  
 (iv) Art Gallery.  
 (v) Beach Concession Stands/Supplies.  
 (vi) Beauty & Health Supplies/Cosmetic—Wholesale/Retail/Mfg.  
 (vii) Billiard/Pool Parlors.  
 (viii) Building Contractors—Material—Retail/Wholesale.  
 (ix) Candy/Nut Stores—Retail/Wholesale.  
 (x) Clothing Apparel (Children 12 and under)—Retail/Wholesale.  
 (xi) Clothing Manufacturers/Tailoring.  
 (xii) Clubs (Serving Alcoholic Beverages).  
 (xiii) Coin/Stamp Shop.  
 (xiv) Distributors—Variety/Non-Alcoholic Beverages.  
 (xv) Dry Cleaners.  
 (xvi) Fine Arts (Porcelain, Ivory, Oriental Rugs, Paintings, etc.).  
 (xvii) Florist—Wholesale/Retail.  
 (xviii) Garages/Auto Repair/Body Shop.  
 (xix) Gift Stores—(Costume Jewelry \$25.00 Wholesale Limit)—Retail/Wholesale/Mfg.  
 (xx) Hotel/Motel/Rooming House/Apartments.  
 (xxi) Industrial Materials/Iron & Metal Work—Wholesale/Retail/Mfg.  
 (xxii) Laundries.  
 (xxiii) Marine/Aircraft Materials—Sales/Service—Retail/Wholesale/Mfg.  
 (xxiv) Medical (Doctors/Dentist, etc.) Supplies—Wholesale/Retail/Mfg.  
 (xxv) Motorbikes/Bicycles/Moped.  
 (xxvi) Office Supplies/Business Machines/Equipment—Retail/Wholesale/Mfg.  
 (xxvii) Pet Stores/Kennels—Supplies.  
 (xxviii) Restaurants.  
 (xxix) Savings/Loans/Bank and Other Financial Institutions excluding Check Cashing.  
 (xxx) Schools (Profit) Day Care Centers/Studios.  
 (xxxi) Specialized Clothing (Sportswear/Lingerie/Accessories/etc.)—Wholesale/Retail/Mfg.  
 (xxxii) Stationery/Books/Printing/Engraving/Paper—Plastic Products—Retail/Wholesale/Mfg.  
 (xxxiii) Tavern/Bar/Lounge.  
 (4) Local alarm systems shall be required for the following businesses:  
 (i) Auto Parts—Sales/Service—Wholesale/Retail/Mfg.

(ii) Beauty/Barber Shops.  
 (iii) Check Cashing Agency/Money Exchange—Collectors.  
 (iv) Discos/Dance Halls/Pavilions.  
 (v) Donut/Pastry/Coffee/Ice Cream—(Seated Service).  
 (vi) Fast Food/Bakery/Ice Cream—(carry out).  
 (vii) Flea Markets/Auction Houses.  
 (viii) Fruit/Vegetable/Newspaper Stands.  
 (ix) Funeral Homes.  
 (x) Golf and Other Sports Professionals.  
 (xi) Health Clubs/Spas/Massage Parlors.  
 (xii) Nursing Homes/Convalescent.  
 (xiii) Parking Lots/Rental Cars/Carwash/Taxi Office.  
 (xiv) Photographers Studios.  
 (xv) Professional/Specialized Services (Lawyers/Accountants/etc./Couriers/Housekeeping/etc.).  
 (xvi) Radio/TV/Stereo/Electronic Equipment/Computers—(Service Only).  
 (xvii) Realty/Insurance/Travel/Employment (Agencies).  
 (xviii) Security/Locksmiths/Alarms—Retail/Wholesale/Mfg.  
 (xix) Vending Machines—Sales/Rentals/Mfg.

## PART 83—COVERAGE, RATES AND PRESCRIBED POLICY FORMS

### Subpart B—Commercial Crime Insurance Coverage

5. Section 83.24 entitled "Classification of commercial risk" is amended by revising the last sentence in paragraph (a) and by revising paragraph (d) as follows:

#### § 83.24 Classification of commercial risks.

(a) \* \* \* For example, a business with the following types of merchandise inventoried, 60% handbags and wigs, and 40% fine jewelry, shall be classified as Class 5 Fine Jewelry.

(d) The following business classifications shall be applicable to the Commercial Crime Insurance Policy:

#### CLASSIFICATION/ALARM LISTING

Premium Code	Class	Description	Alarm type
A1	3	All risks not otherwise classified	3
02	3	Amusement enterprise	3
B1	2	Antique store	3
C1	4	Art gallery	3
33	5	Art supplies (retail, wholesale, mfg.)	2
D1	2	Auto parts/no service (retail, wholesale, mfg.)	2
03	2	Auto parts/sales/service (retail, wholesale, mfg.)	4
47	2	Beach concession stands/supplies	3
32	2	Beauty/barber shops	4

#### CLASSIFICATION/ALARM LISTING—Continued

Premium Code	Class	Description	Alarm type
41	2	Beauty & health supplies/cosmetic (retail, wholesale, mfg.)	3
C6	4	Beer/wine with food (retail)	2
F1	6	Beer/wine (wholesale)	1
04	4	Billiard/pool parlors	3
70	6	Boutiques	1
05	2	Bowling lanes/centers/skating rinks	0
34	2	Building contractors/materials (retail, wholesale, mfg.)	3
06	4	Cameras/photo supplies/film processing (retail, wholesale, mfg.)	1
43	2	Candy/nuts stores (retail, wholesale)	3
G3	4	Check cashing agency/money exchange/collectors	4
J1	1	Churches/charities/nonprofit org./public properties	0
36	4	Clothing apparel/children 12 & under (retail, wholesale)	3
11	5	Clothing manufacturer/tailoring	3
22	5	Clothing/men's (age 12 & over) (retail, wholesale)	1
30	5	Clothing/women's (age 12 & over) (retail, wholesale)	1
07	4	Clubs (serving alcoholic beverages)	3
K1	3	Coin/stamp shop	3
08	2	Discos/dance halls/pavilions	4
50	2	Distributors-variety/non-alcoholic beverages	3
C5	3	Donut/pastry/coffee/ice cream shop (seated service)	4
09	4	Drug stores/druggist's sundries	1
L1	3	Drugs (wholesale)	2
10	4	Dry cleaners	3
38	3	Dry goods/textile/sewing material (retail, wholesale, mfg.)	2
11	3	Electric appliances/appliances/parts (retail, wholesale, mfg.)	1
E1	2	Fast food/bakery/donut, ice cream (carryout only)	4
39	2	Fine arts, porcelain/ivory/oriental rugs/paintings/etc.	3
78	2	Flea markets/auction houses	4
40	2	Florist (retail, wholesale)	3
M1	4	Food stalls (wholesale)	1
N1	2	Fruit/vegetable/newspaper stands	4
45	2	Funeral homes	4
42	2	Furniture/home furnishings/floor covering/upholstery now or used (retail, wholesale, mfg.)	3
12	4	Furnishings (retail, wholesale, mfg., storage)	2
13	3	Garages/auto repair/body shops	3
14	3	Gasoline service station/tire dealers	1
44	2	Gift store/costume jewelry \$25.00 wholesale limit (retail, wholesale, mfg.)	3
15	2	Golf and other professional sports shops	4
16	4	Grocery stores/delicatessen/health food store	2
17	6	Guns/ammunition (retail, wholesale, mfg.)	2
46	3	Hardware/housewares (retail, wholesale, mfg.)	2
C2	2	Health clubs/spas/massage parlors	4
80	2	Hobby shops/toys/novelty (retail, wholesale, mfg.)	2
48	2	Hotel/motel/rooming house/apartments	3
01	2	Industrial materials/iron & metal work (retail, wholesale, mfg.)	3
18	5	Jewelry (retail, wholesale, mfg., storage)	1
19	2	Laundries	3
52	2	Leather products (retail, wholesale, mfg.)	2
20	5	Liquor sales (retail)	1
P1	5	Liquor (wholesale)	2
37	3	Marine/aircraft materials (bakery service) (retail, wholesale, mfg.)	3
21	2	Meat/poultry/fish dealers	2
54	2	Medical supplies (doctors, dentists, etc.) (retail, wholesale, mfg.)	3



## CLASSIFICATION/ALARM LISTING—Continued

Premium		Description	Alarm type
Code	Class		
01	2	Motorbikes/bicycles/mopeds	3
56	3	Music stores/instruments/supplies (retail, wholesale, mfg.)	2
35	2	Nursing/convalescent homes	4
C3	2	Office supplies/business machines/equipment (retail, wholesale, mfg.)	3
58	3	Parking lots/rental cars/carwash/taxi offices	4
23	4	Pawn brokers	1
76	2	Pet stores/kennels/supplies	3
R1	2	Photographers studios	4
51	6	Precious metals/electroplating/storage	2
C8	6	Precious metals/electroplating (retail, wholesale, mfg.)	1
74	2	Professional/specialized services (lawyers, accountants, couriers, housekeeping, etc.)	4
24	5	Radio/TV/stereo/electronic equipment/computers (retail, wholesale, mfg.)	1
C4	2	Radio/TV/stereo/electronic equipment/computers (service only)	4
62	2	Realty/insurance/travel/employment agencies	4
T1	3	Record shop	1
25	3	Restaurant/caterer	3
26	4	Savings/loans/banks & other financial institutions excluding check cashing	3
66	2	Schools (profit)/day care centers/studios	3
84	2	Security/locks/mirrors/alarms (retail, wholesale, mfg.)	4
88	5	Shoe stores (retail, wholesale, mfg.)	2
H1	5	Specialized clothing (sportswear/lingerie/accessories/etc.) (retail, wholesale, mfg.)	3
U1	5	Sports goods/general (retail, wholesale, mfg.)	2
60	2	Stationery/books/printing/engraving/paper or plastic products (retail, wholesale, mfg.)	3
27	4	Tavern/bar/lounge	3
V1	3	Taxi/limousines (robbery only)	0
28	2	Theatre	0
29	4	Tobacco dealers (retail)	2
C9	4	Tobacco dealers (wholesale)	1
72	5	Used clothing/shoe repair/thrift shops	1
W1	6	Variety stores/department stores	1
X1	2	Vending machines (sales/rentals/mfg.)	4
V1	4	Wig shops	2

6. Section 83.24a entitled "Gross receipts" is amended by revising paragraphs (f) and (i) as follows:

## § 83.24a Gross receipts.

(f)(1) A warehouse operated as a distribution center for store(s) under common ownership and management shall report the total gross receipts of the store(s) it supplies. If a warehouse supplies more than one store, it shall report the sum of the gross receipts figures for all the stores it supplies. If more than one warehouse supplies one store, the gross receipts figure applicable to the store shall be apportioned among the warehouses according to the percentage the value of merchandise supplied by each warehouse bears to the total value of merchandise supplied.

(2) A warehouse operated as a distribution center for store(s) not under common ownership and management shall report the total gross receipts of the warehouse only, if the business is taxed on gross receipts.

(3) A warehouse operated as a distribution center for store(s) not under common ownership and management shall report the "Total Income" line of the tax return as derived from interest, rents, capital gains, other, etc., if the business is not taxed on gross receipts.

(i) Any questions regarding gross receipts or unique or unusual risk requiring special rating treatment shall be submitted to the servicing company listed in § 80.6 of this chapter for rate quotation.

7. Section 83.25 entitled "Commercial Crime Insurance Rates" is revised in its entirety and shall now read as follows:

## § 83.25 Commercial Crime Insurance Rates.

(a) Premium rates for Commercial Crime Insurance Policies for risks shall be determined by reference to the rate charts contained in paragraph (e) of this section. The annual gross receipts shall be determined in accordance with § 83.24(a).

(b) Option 1: An applicant may apply for insurance coverage under Insuring Agreements I, II, III, IV, and VII of the Commercial Policy dealing with Safe Burglary, Theft from Night Depository, and Burglary or Robbery of a Watchman, and Damage resulting from losses under Insuring Agreements I and VII only. Such coverage shall be referred to as Option 1.

(c) Option 2: An applicant may apply for insurance coverage under Insuring Agreements V, VI, VII, and VIII of the Commercial Policy dealing with Robbery and Observed Theft inside and outside the premises and Damage resulting from losses under Insuring Agreements V and VI only. Such coverage shall be referred to as Option 2.

(d) Option 3: An applicant may apply for insurance coverage under all of the Insuring Agreements I, II, III, IV, V, VI, and VII of the Commercial Crime Insurance Policy. This Option provides for uniform as well as varying limits of coverage under Option 1 and 2 but only in the same policy. Both Options 1 and 2 must be applied for at the same time. If one of the options has been selected the other option may be added upon a renewal or upon an endorsement of the original policy. A discount will be provided for Combined Coverage, Option 3.

(e) The following tables shall be used to determine rates for commercial risks.

## ANNUAL PREMIUMS

Gross receipts	Amount of insurance											
	Less than \$100,000		\$100,000 to \$199,000		\$200,000 to \$299,999		\$300,000 to \$499,999		\$500,000 to \$999,999		\$1,000,000 or greater	
	Option		Option		Option		Option		Option		Option	
	1	2	1	2	1	2	1	2	1	2	1	2
Class 1												
\$1,000	\$78	\$106	\$116	\$160	\$118	\$180	\$158	\$212	\$194	\$262	\$310	\$420
\$2,000	146	190	222	284	222	284	296	378	368	472	588	756
\$3,000	218	274	326	410	326	410	434	546	542	682	868	1,090
\$4,000	282	348	424	522	424	522	566	696	706	888	1,128	1,368
\$5,000	334	394	502	592	502	592	658	788	834	984	1,336	1,574
\$6,000	352	432	528	648	528	648	704	864	880	1,078	1,406	1,724
\$7,000	366	460	548	690	548	690	732	900	912	1,146	1,460	1,826
\$8,000	380	488	568	732	568	732	758	974	946	1,216	1,514	1,948
\$9,000	384	498	576	748	576	748	766	994	956	1,240	1,530	1,984
\$10,000	392	516	588	774	588	774	784	1,030	978	1,266	1,566	2,056
\$11,000	414	562	622	844	622	844	828	1,124	1,034	1,404	1,656	2,246
\$12,000	432	600	648	900	648	900	864	1,198	1,078	1,466	1,726	2,304
\$13,000	442	618	662	928	662	928	882	1,236	1,100	1,542	1,762	2,480
\$14,000	446	628	668	942	668	942	890	1,254	1,112	1,566	1,780	2,506
\$15,000	450	636	676	956	676	956	900	1,272	1,124	1,590	1,796	2,544



## ANNUAL PREMIUMS—Continued

Gross receipts	Amount of insurance											
	Less than \$100,000		\$100,000 to \$199,000		\$200,000 to \$299,999		\$300,000 to \$499,999		\$500,000 to \$999,999		\$1,000,000 or greater	
	Option		Option		Option		Option		Option		Option	
	1	2	1	2	1	2	1	2	1	2	1	2
Class 2												
\$1,000	94	134	142	200	142	200	188	266	234	330	374	526
\$2,000	176	240	266	358	266	358	354	476	442	594	706	950
\$3,000	260	344	390	516	390	516	520	688	648	858	1,038	1,372
\$4,000	338	438	506	658	506	658	674	876	842	1,092	1,348	1,748
\$5,000	396	496	598	746	598	746	796	992	994	1,238	1,550	1,982
\$6,000	420	544	632	816	632	816	840	1,086	1,050	1,356	1,680	2,170
\$7,000	438	578	686	888	686	888	874	1,156	1,092	1,444	1,746	2,310
\$8,000	454	614	682	922	682	922	908	1,220	1,134	1,532	1,814	2,450
\$9,000	460	626	690	938	690	938	920	1,250	1,148	1,560	1,836	2,498
\$10,000	472	650	706	974	706	974	942	1,298	1,176	1,620	1,882	2,592
\$11,000	500	708	750	1,062	750	1,062	998	1,414	1,246	1,766	1,994	2,826
\$12,000	522	754	782	1,132	782	1,132	1,044	1,508	1,302	1,884	2,084	3,014
\$13,000	534	778	800	1,168	800	1,168	1,066	1,556	1,330	1,942	2,128	3,106
\$14,000	538	790	808	1,184	808	1,184	1,076	1,578	1,344	1,972	2,150	3,154
\$15,000	544	802	816	1,202	816	1,202	1,088	1,602	1,358	2,000	2,174	3,200
Class 3												
\$1,000	106	140	160	208	160	208	212	276	262	344	420	550
\$2,000	198	248	298	374	298	374	396	468	494	618	790	990
\$3,000	292	358	438	538	438	538	582	716	726	894	1,162	1,428
\$4,000	376	456	568	684	568	684	756	912	942	1,138	1,508	1,820
\$5,000	446	518	668	776	668	776	890	1,034	1,110	1,290	1,776	2,064
\$6,000	470	566	706	850	706	850	940	1,130	1,174	1,412	1,878	2,258
\$7,000	490	602	736	904	736	904	980	1,204	1,222	1,504	1,956	2,404
\$8,000	510	640	764	958	764	958	1,018	1,278	1,270	1,594	2,032	2,552
\$9,000	516	652	774	978	774	978	1,030	1,302	1,286	1,626	2,058	2,600
\$10,000	528	676	792	1,014	792	1,014	1,056	1,350	1,318	1,686	2,110	2,698
\$11,000	560	736	840	1,108	840	1,108	1,120	1,472	1,398	1,838	2,238	2,942
\$12,000	586	786	880	1,178	880	1,178	1,172	1,570	1,462	1,960	2,340	3,136
\$13,000	598	810	898	1,216	898	1,216	1,196	1,618	1,494	2,022	2,392	3,224
\$14,000	606	822	908	1,234	908	1,234	1,210	1,644	1,510	2,052	2,416	3,284
\$15,000	612	834	916	1,252	916	1,252	1,222	1,668	1,526	2,082	2,442	3,332
Class 4												
\$1,000	118	144	178	216	178	216	236	288	294	358	470	572
\$2,000	222	258	334	388	334	388	444	516	554	642	866	1,028
\$3,000	326	372	490	560	490	560	652	744	812	928	1,300	1,498
\$4,000	424	474	638	712	634	712	846	948	1,054	1,182	1,688	1,892
\$5,000	498	538	748	806	748	806	996	1,074	1,242	1,340	1,888	2,144
\$6,000	528	588	790	862	790	862	1,054	1,176	1,314	1,468	2,102	2,348
\$7,000	548	626	822	940	822	940	1,096	1,252	1,368	1,562	2,190	2,500
\$8,000	570	664	856	996	856	996	1,140	1,328	1,422	1,658	2,276	2,652
\$9,000	578	678	886	1,016	886	1,016	1,154	1,354	1,440	1,690	2,304	2,702
\$10,000	592	702	888	1,054	888	1,054	1,182	1,404	1,476	1,752	2,362	2,804
\$11,000	628	766	942	1,148	942	1,148	1,254	1,530	1,586	1,912	2,506	3,058
\$12,000	656	816	984	1,226	984	1,226	1,312	1,632	1,638	2,038	2,620	3,260
\$13,000	670	842	1,006	1,264	1,006	1,264	1,340	1,682	1,674	2,102	2,678	3,362
\$14,000	678	854	1,018	1,282	1,018	1,282	1,356	1,708	1,692	2,134	2,708	3,412
\$15,000	686	866	1,028	1,302	1,028	1,302	1,370	1,734	1,710	2,164	2,736	3,464
Class 5												
\$1,000	112	128	170	192	170	192	224	256	260	316	446	508
\$2,000	208	230	314	344	314	344	416	458	518	570	830	912
\$3,000	304	330	456	496	456	496	606	660	758	882	1,214	1,316
\$4,000	392	420	580	630	590	630	784	840	978	1,048	1,566	1,678
\$5,000	458	476	686	714	686	714	914	952	1,140	1,188	1,826	1,900
\$6,000	488	522	732	782	732	782	976	1,042	1,218	1,300	1,950	2,080
\$7,000	512	556	768	832	768	832	1,022	1,110	1,276	1,384	2,042	2,218
\$8,000	534	588	802	884	802	884	1,068	1,176	1,334	1,468	2,134	2,350
\$9,000	542	600	814	900	814	900	1,084	1,200	1,354	1,496	2,169	2,394
\$10,000	558	622	838	934	838	934	1,116	1,244	1,392	1,554	2,228	2,464
\$11,000	596	678	896	1,018	896	1,018	1,192	1,356	1,488	1,694	2,382	2,710
\$12,000	628	724	942	1,086	942	1,086	1,254	1,448	1,568	1,806	2,508	2,890
\$13,000	644	746	964	1,120	964	1,120	1,286	1,492	1,604	1,862	2,568	2,980
\$14,000	650	758	976	1,136	976	1,136	1,300	1,514	1,625	1,890	2,598	3,024
\$15,000	658	768	988	1,152	988	1,152	1,316	1,536	1,644	1,918	2,630	3,070
Class 6												
\$1,000	114	114	170	172	170	172	226	228	280	284	450	454
\$2,000	210	206	314	306	314	306	418	410	520	512	832	818
\$3,000	304	296	456	444	456	444	608	592	758	738	1,214	1,180
\$4,000	392	378	588	566	588	566	782	754	976	940	1,562	1,504
\$5,000	454	428	682	642	682	642	908	854	1,134	1,066	1,814	1,708
\$6,000	488	468	730	702	730	702	974	934	1,216	1,166	1,944	1,868
\$7,000	512	498	768	748	768	748	1,022	996	1,278	1,242	2,042	1,988
\$8,000	526	528	804	792	804	792	1,072	1,056	1,338	1,318	2,140	2,108
\$9,000	544	538	816	808	816	808	1,088	1,076	1,358	1,342	2,172	2,148
\$10,000	560	558	840	838	840	838	1,120	1,116	1,398	1,394	2,236	2,230
\$11,000	602	608	902	914	902	914	1,202	1,216	1,500	1,520	2,400	2,430



## ANNUAL PREMIUMS—Continued

Gross receipts	Amount of insurance											
	Less than \$100,000		\$100,000 to \$199,999		\$200,000 to \$299,999		\$300,000 to \$499,999		\$500,000 to \$999,999		\$1,000,000 or greater	
	Option		Option		Option		Option		Option		Option	
	1	2	1	2	1	2	1	2	1	2	1	2
\$12,000	634	650	950	974	950	974	1,266	1,298	1,580	1,620	2,530	2,592
\$13,800	650	670	974	1,004	974	1,004	1,298	1,338	1,622	1,670	2,594	2,672
\$14,000	658	680	986	1,020	986	1,020	1,314	1,358	1,642	1,696	2,626	2,714
\$15,000	666	690	1,000	1,034	1,000	1,034	1,332	1,378	1,662	1,720	2,660	2,754

(1) Option 1: Burglary Only.

(2) Option 2: Robbery Only.

(3) Option 3: A combination of Options 1 and 2 in uniform or varying amounts.

(4) See Discount Page for applicable multipliers and discounts.

(f) If the premises are protected by an acceptable burglar alarm system or Class E safe, premium discounts shall be permitted as follows:

## ALARM/SAFE CREDITS

Alarm system	Safe type	
	Class E	Other
None	.85	1.00
Local	.75	.90
Silent	.70	.80
Central Station	.65	.75
Central Station With Guard	.60	.70

Note.—Multiply the Burglary rate by the appropriate factor.

## Package Discount

Apply a factor of .90 to the total premium if both burglary and robbery are purchased.

## § 83.26 [Amended]

8. Section 83.25, paragraph (b) entitled "Commercial Crime Insurance Policy Form" is amended in the following respects:

A. The paragraph entitled "Insuring Agreements" is amended to read as follows:

## Option 1 (Burglary Only Including Safe Burglary)

Option 1 includes insurance coverage only under the individually numbered insuring Agreements I, II, III, and IV listed below.

## I. Burglary: Robbery of a Watchman

To pay for loss by burglary or by robbery of a watchman, while the named premises are not open for business, of merchandise, furniture, fixtures and equipment within the named premises provided that this Insuring Agreement does not extend to the loss of money or securities or to cash value in excess of \$50 for any item of jewelry unless such property is forcibly extracted from a locked safe as provided under Insuring Agreement II entitled "Safe Burglary" which follows:

## II. Safe Burglary

To pay for loss by safe burglary of money, securities and merchandise within the named premises while the premises are not open for business, but no payment shall be made for loss not forcibly extracted from a locked safe, nor by a loss in excess of \$5,000 except with

respect to loss by safe burglary of a safe rated for burglary resistance as Class E or better weighing at least seven hundred and fifty pounds or securely anchored to the floor.

## III. Damage

To pay for damage to the named premises and to money, securities, merchandise, furniture, fixtures and equipment within the named premises by burglary, robbery of a watchman, safe burglary or attempt thereof provided the insured is the owner thereof or is liable for such damage.

## IV. Policy Period, Territory

To pay for losses under Insuring Agreements I, II, and III only when occurring during the policy period within a state, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and such other territories or possessions of the United States, including the Trust Territory of the Pacific Islands, as defined in 12 U.S.C. 1749bbb-10a et seq. and set forth in 44 CFR Part 80 et seq.

## Option 2 (Robbery Only)

Option 2 includes insurance coverage only under the individually numbered insuring Agreement V, VI, VII and VIII listed below.

## V. Robbery, Including Observed Theft Inside the Premises

To pay for loss by robbery or observed theft of money, securities, merchandise, furniture, fixtures, and equipment within the named premises.

## VI. Robbery, Including Observed Theft, Outside of the Premises

To pay for loss by robbery or observed theft of money, securities, and merchandise, including the wallet or bag containing such property while such property is in conveyance by the insured or his messenger outside the named premises, but no payment shall be made for any loss in excess of \$5,000 except when the insured or his messenger is accompanied by a guard armed with a firearm. The person carrying the insured property and the armed guard cannot be same person.

This Insuring Agreement includes theft from a night depository but only if a deposit of money has been made at a night depository of a banking institution by a bonded armored car messenger service.

## VII. Damage

To pay for damage to the named premises and to money, securities, merchandise, furniture, fixtures and equipment within the named premises, by robbery, or attempt thereof, provided the insured is the owner thereof or is liable for such damage.

## VIII. Policy Period, Territory

To pay for losses under Insuring Agreements V, VI, VII only when occurring during the policy period within a state, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and such other territories or possessions of the United States including the Trust Territory of the Pacific Islands, as defined in 12 U.S.C. 1749bbb-10a et seq. and set forth in 44 CFR Part 80 et seq.

## Option 3 (Robbery and Burglary in Uniform and Varying Amounts)

Option 3 shall provide for uniform and varying limits of coverage under Option 1 and 2 but only in the same policy. Both Option 1 and 2 must be applied for at the same time.

If one of the options has been selected, the other option may be added upon a renewal or upon an endorsement of the original policy. A discount will be provided for Combined Coverage, Option 3.

B. The paragraph entitled "Exclusions" is amended so that subparagraph (d) is read as follows:

This policy does not apply:

(d) under Insuring Agreement I and II to loss occurring during a fire in the premises.

9. Paragraph 1 of the Commercial Insurance Policy under the heading "Conditions" is amended as follows:

A. Subparagraph 8, "No benefit to bailee," is removed.

B. This Section headed "Conditions" is further amended by redesignating paragraphs (9)-(15) as paragraphs (8)-(14), respectively.

These amendments issued under 12 U.S.C. 1749bbb-17.

Issue Date: April 10, 1985.

Jeffrey S. Bragg,

Administrator, Federal Insurance Administration.

[FR Doc. 85-9901 Filed 4-25-85; 8:45 am]

BILLING CODE 6718-05-M



# FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Parts 81 and 83

[PR Docket No. 84-1236; FCC 85-187]

### Eligibility for Portable Ship Station Licenses and Frequency Assignments on the Great Lakes

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document amends four rule sections in the maritime services. The purpose of these amendments is to eliminate interference to the ship movement service on the Great Lakes and to prevent inadvertent unlicensed operations by boaters. This action is a result of the Commission's ongoing effort to review and update the rules.

**EFFECTIVE DATE:** May 28, 1985.

**FOR FURTHER INFORMATION CONTACT:** James A. Shaffer, Private Radio Bureau, (202) 632-7197.

#### SUPPLEMENTARY INFORMATION:

#### List of Subjects

##### 47 CFR Part 81

Coast stations, Marine safety, Radio.

##### 47 CFR Part 83

Canada, Communications equipment, Ship stations, Radio.

#### Report and Order (Proceeding Terminated)

In the matter of amendments of parts 81 and 83 concerning eligibility for portable ship station licenses and frequency assignments on the Great Lakes; PR Docket No. 84-1236, FCC 85-187.

Adopted: April 15, 1985.

Released: April 19, 1985.

By the Commission.

1. This Report and Order amends Parts 81 and 83 of the Commission's rules to: (1) Eliminate granting portable ship station licenses to entities which solely install or service marine radio equipment, and (2) designate marine VHF Channels 11, 12, 13 and 14 primarily available for ship movement service communications in the Great Lakes.

#### Portable Ship Station License

2. Currently § 83.50(b) of our rules permits a ship station license to be granted solely for testing marine radio equipment incident to installation or servicing. Boat owners frequently assume that after a service company installs and tests a radio it is appropriately licensed and available for use. This mistake results in inadvertent

unlicensed operations. Since the ship station application procedure has been simplified to permit "instant" operating authority at the time the application is mailed<sup>1</sup> there is no need for a service company to test a newly installed radio under its own portable ship station license. This can be done under the authority granted by concurrently completing the combined application form, FCC Form 506 and 506-A (Application for Ship Radio Station License). Therefore, in the Notice of Proposed Rule Making<sup>2</sup> in this proceeding, we proposed to discontinue granting portable ship station licenses to entities solely installing or servicing marine radio equipment. We received no comments addressing this proposal. For the reasons indicated above, we are amending § 83.50(b) as proposed.

3. Existing portable ship station licensees which solely install or service marine radio equipment will be permitted to continue to operate under their license for the remainder of their license term. We will emphasize in a Public Notice the boat owner/operator responsibilities to complete FCC Forms 506 and 506-A prior to installing, testing and operating a new marine radio. Additionally, we are correcting § 83.28(a)(1) to state that FCC Form 506-A provides temporary authority to operate for 90 days rather than 60 days.

#### Great Lakes Ship Movement Service

4. In response to reports of interference on ship movement channels in some areas of the Great Lakes we proposed in the Notice to make marine VHF Channels 11, 12, 13 and 14 primarily available for ship movement service communications. The ship movement service is part of the safety system established on the Great Lakes by the Canadian and U.S. Coast Guards. VHF Channels 11, 12, 13 and 14, are designated by the Great Lakes Agreement<sup>3</sup> as ship movement channels. Channels 11, 12 and 14 are also used for commercial and port operations communications. The Lake Carriers' Association, the United States Coast Guard, and Canada's Department of Communications filed comments on this proposal. No reply comments were received.

5. The commenters supported the proposed amendments but noted an ongoing issue concerning the future use

of Channel 13 in the Great Lakes. The Vessel Bridge-to-Bridge Radiotelephone Act<sup>4</sup> requires that certain classes of vessels use Channel 13 for communications from one vessel's bridge to another vessel's bridge concerning navigational matters. However, in the Great Lakes under a waiver Channel 16 is used for bridge-to-bridge communications. Channel 16 has become congested in some areas. For this reason, the U.S. Coast Guard is currently discussing with the Canadian authorities the use of Channel 13 for bridge-to-bridge communications in the Great Lakes. Therefore, U.S. Coast Guard suggested minor changes in the proposed amendments which would accommodate any future changes in the use of Channel 13 in the Great Lakes.

6. As pointed out in the Notice, there are ten other frequencies available for commercial communications on a primary basis in the Great Lakes while five additional frequencies are available for port operations communications. On a secondary basis, Channel 11 would continue to be available for commercial communications and Channels 12 and 14 for port operations communications. No licensee will be without a suitable alternative frequency if secondary status is unsatisfactory in a particular area. Therefore, we are amending the rules substantially as proposed. However, as suggested by the U.S. Coast Guard we have made minor changes to §§ 81.356 and 83.351 concerning the use of Channel 13 in the Great Lakes. If Channel 13 ultimately becomes the Great Lakes bridge-to-bridge channel we will initiate appropriate rule making.

7. Pursuant to section 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), we certify that these rules will not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of the installation or servicing of ship radio stations is performed under the ship station license. The purpose of these rule amendments is to prevent unlicensed station operations by uninformed boat operators and to prevent interference to ship movement communications on the Great Lakes. No economic impact will result.

8. The amendments contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or record keeping, labeling, disclosure, or record retention requirements; and will not increase or decrease burden hours imposed on the public.

<sup>1</sup> See, *Order*, FCC 78-846, released January 11, 1979, 70 FCC 2d 863.

<sup>2</sup> PR Docket No. 84-1236, FCC 84-580, released November 28, 1984, 49 FR 47641.

<sup>3</sup> Agreement between the United States of America and Canada for the Promotion of Safety on the Great Lakes, 1973, TIAS 7837, amended, 1978, TIAS 9352.

<sup>4</sup> 33 U.S.C. 1201 et seq.



9. Accordingly, it is ordered, That under the authority contained in sections 4(i) and 303 (c) and (r) of the Communications Act of 1934, as amended, 47 U.S.C. 154 (i) and 303(c) and (r), the Commission's rules are amended as set forth in the attached Appendix, effective May 28, 1985.

10. It is further ordered, That a copy of this Report and Order shall be sent to the Chief Counsel for Advocacy of the Small Business Administration.

11. It is further ordered, That this proceeding is terminated.

12. Regarding questions on matters covered in this document contact James Shaffer (202) 632-7197.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303.)

Federal Communications Commission.

William J. Tricarico,

Secretary.

#### Appendix

Parts 81 and 83 of Chapter 1 of Title 47 of the Code of Federal Regulations are amended as follows:

#### PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA FIXED SERVICE

A. In § 81.356(a), the tables for Port Operations, Commercial and Navigational frequencies are amended by revising the channel designators 12, 73, 14, 11 and 13 and paragraphs (b)(4) and (b)(13) are added as follows:

#### § 81.356 Assignable frequencies in the band 156-162 MHz.

(a) \* \* \*

Channel designator	Frequencies (MHz)		Points of communications	Conditions of use
	Coast	Ship		
12	156.600	156.600	do	1, 4
73	156.675	156.675	do	
14	156.700	156.700	do	1, 4
11	156.550	156.550	Coast to ship	1, 4
13	156.650	156.650	Coast to ship	10, 13

(b) \* \* \*

(4) In the Great Lakes available primarily for use for the Ship Movement Service (SMS) appropriate to the area of operation. On a secondary basis, available for use as permitted elsewhere in these rules.

(13) In the Great Lakes, available for use in the Ship Movement Service in sectors designated by St. Lawrence Seaway Development Corporation.

#### PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

##### § 83.28 [Amended]

B. 1. In § 83.28 paragraph (a)(1) is amended by changing the number 60 to 90 in the last sentence.

##### § 83.50 [Amended]

2. In § 83.50 paragraph (b) is amended by removing the words "installation or servicing" from the first sentence.

3. In § 83.351(a) the table is amended by revising the entries for 156.550 through 156.700, and paragraphs (b)(53) and (b)(54) are added and reserved, and paragraphs (b)(55) and (b)(56) are added to read as follows:

#### § 83.351 Frequencies available.

(a) \* \* \*

Carrier frequency	Section	Conditions of Use limitations
156.550	83.359, 83.361, 83.539	19, 20, 27, 35, 55
156.575	83.359	19, 20, 28, 32
156.600	83.359, 83.361, 83.539	19, 20, 23, 35, 55
156.625	83.359	19, 20, 30, 46
156.650	83.359	19, 20, 24, 31, 36, 55, 56
156.675	83.359	19, 20, 23
156.700	83.359, 83.361, 83.539	19, 20, 23, 35, 55

(b) \* \* \*

(53) [Reserved]

(54) [Reserved]

(55) In the Great Lakes available primarily for the Ship Movement Service (SMS) appropriate to the area of operation. On a secondary basis available for use as permitted elsewhere in these rules.

(56) In the Great Lakes, available for use in the Ship Movement Service (SMS) in sectors designated by St. Lawrence Seaway Development Corporation.

[FR Doc. 85-9850 Filed 4-25-85; 8:45 am]

BILLING CODE 6712-01-M



# Proposed Rules

Federal Register

Vol. 50, No. 81

Friday, April 25, 1985

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

#### 7 CFR Part 400

[Doc. No. 2104S]

#### General Administrative Regulations; Reinsurance Agreement

**AGENCY:** Federal Crop Insurance Corporation, USDA.

**ACTION:** Proposes rule.

**SUMMARY:** The Federal Crop Insurance Corporation (Corporation) proposes to issue a new Subpart J in Chapter IV of Title 7 of the Code of Federal Regulations (CFR), to be known as 7 CFR Part 400—General Administrative Regulations—Subpart J. Reinsurance Agreement. The intended effect of this rule is to prescribe procedures applicable to operations under a Reinsurance Agreement with the Corporation. The authority for the promulgation of this rule is contained in the Federal Crop Insurance Act, as amended.

**DATE:** Written comments, data, and opinions on this proposed rule must be submitted not later than May 28, 1985, to be sure of consideration.

**ADDRESS:** Written comments on this proposed rule should be sent to the Office of the Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

**FOR FURTHER INFORMATION CONTACT:** Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 447-3325.

**SUPPLEMENTARY INFORMATION:** This action has been reviewed under USDA procedures established by Departmental Regulation No. 1512-1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date

established for these regulations is March 1, 1990.

Merritt W. Sprague, Manager, FCIC, has determined that this action (1) is not a major rule as defined by Executive Order No. 12291 (February 17, 1981), because it will not result in: (a) An annual effect on the economy of \$100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) will not increase the Federal paperwork burden for individuals, small businesses, and other persons.

The title and number of the Federal Assistance Program to which this proposed rule applies are: Title—Crop Insurance; Number 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

#### Background

The Federal Crop Insurance Corporation, an agency of the United States Department of Agriculture, is authorized by the Federal Crop Insurance Act, as amended (Act) (7 U.S.C. 1501 *et seq.*), to offer programs of crop insurance to American farmers, the regulations for which are found in Title 7 of the Code of Federal Regulations (7 CFR Part 400 *et seq.*).

Section 508(a) of the Federal Crop Insurance Act, as amended by Pub. L. 80-320, August 1, 1947, provided, commencing with crops planted for harvest in 1948, for reinsurance of insurers of producers of agricultural commodities and that such reinsurance

be limited to contracts covering farms in not more than 20 counties. (7 U.S.C. 1508(a)).

On July 23, 1957, Pub. L. 85-111 added a new subsection 508(f) to the Act providing for reinsurance of crop insurance in Puerto Rico written by an agency of the Puerto Rican Government on any crop or plantation should private reinsurance become unavailable. (7 U.S.C. 1508(f)).

Amendments to the Act in 1980, contained in Pub. L. 96-365, dated September 26, 1980, provided in Subsection 508(e) that, to the maximum extent possible, consistent with Subsections (a) and (b) of Section 508 and with sound reinsurance principles, reinsurance be offered to insurers including private insurance companies or pools of such companies, and reinsurers of such companies that insure producers of any agricultural commodity under any plan acceptable to the Corporation. (7 U.S.C. 1508(e)).

Section 508(f) was also amended by Pub. L. 96-365 to provide reinsurance for production of agricultural commodities in the Commonwealth of Puerto Rico, Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, in the same manner as provided for agricultural products in the United States. (7 U.S.C. 1508(f)).

There has been a steady increase in the volume of crop insurance sold through commercial channels since the passage of the 1980 amendments to the act. Since 1981, premium income on reinsured paper has gone from \$12.8 million to an estimated \$378 million for crop year 1985, an increase of 2,900 percent. During the same period, the share of business written by reinsured companies compared with government operations, including agents and private insurance companies under Agency Sales and Service Agreements, rose from 3 percent to 70-80 percent by available estimates.

The proposed Standard Reinsurance Agreement sets forth the terms and conditions under which the Corporation will reinsure all eligible crop insurance policies sold or reinsured by insurance companies. All such policies must be written on terms, including premium rates, approved by the Corporation, and may only be issued on crops and in areas approved by the Corporation. All



participating insurance companies must submit a plan of operation for the Corporation's approval.

The policies must be made available to all eligible producers by the participating insurance companies. In the administration of the Agreement, the Corporation must be provided all relevant information, including a list of all applicants refused coverage and all producers cancelled from insurance, along with the reason for such action. All loss adjustment methods will be prescribed by the Corporation and only licensed agents or brokers may sell policies covered by the Agreement. The Corporation may, at any time, suspend its obligation to accept additional liability by providing written notice to that effect.

Interested parties may obtain a copy of the proposed Reinsurance Agreement for the 1985-87 reinsurance years by contacting the Office of the Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

Written comments, data, and opinions on this proposed rule should be sent to the Office of the Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

Written comments received pursuant to this notice will be available for public inspection in the Office of the Manager during regular business hours, Monday through Friday.

#### List of Subjects in 7 CFR Part 400

Crop insurance, reinsurance agreement.

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation hereby proposes to add a new Subpart J to Part 400 of Title 7 of the Code of Federal Regulations, to be known as 7 CFR Part 400, Subpart J—General Administrative Regulations; Reinsurance Agreement, containing procedures applicable to insurance companies under a reinsurance agreement with the Corporation, to read as set forth below:

#### PART 400—GENERAL ADMINISTRATIVE REGULATIONS

• • • • •

#### Subpart J—Reinsurance Agreement

- Sec.  
400.75 Availability of Reinsurance Agreements.  
400.76 Eligibility for Reinsurance Agreements.

- Sec.  
400.77 Obligations of the Corporation.  
400.78 Limitations on Corporation's obligations.  
400.79 Obligations of participating Insurance Company.  
400.80 Disputes.  
400.81 OMB control numbers.

Authority: Secs. 506, 516, Pub. L. 75-430, 52 Stat. 73, 77 as amended (7 U.S.C. 1506, 1516).

#### Subpart J—Reinsurance Agreement

##### § 400.75 Availability of reinsurance agreements.

The Federal Crop Insurance Corporation ("Corporation") will offer Reinsurance Agreements to eligible companies under which the Corporation will reinsure policies which the companies issue to producers of agricultural commodities. The Reinsurance Agreement will be consistent with the requirements of the Federal Crop Insurance Act, as amended, and provisions of the regulations of the Corporation found at Chapter IV of Title 7 of the Code of Federal Regulations.

##### § 400.76 Eligibility for reinsurance agreements.

A company will be eligible to participate in an Agreement if the Corporation determines the company meets the financial standards and financial reporting requirements at Subpart G of Part 400 of Title 7 of the Code of Federal Regulations (7 CFR 400.50 *et seq.*)

##### § 400.77 Obligations of the Corporation.

The Reinsurance Agreement will include the following among the obligations of the Corporation.

(a) The Corporation will reinsure policies written on terms, including premium rates, approved by the Corporation, on crops and in areas approved by the Corporation, and in accordance with the provisions of the Federal Crop Insurance Act, as amended, and the provisions of these regulations.

(b) The Corporation will pay a portion of each producer's premium on the policies reinsured under the Reinsurance Agreement, as authorized by the Federal Crop Insurance Act, as amended.

##### § 400.78 Limitations on Corporation's obligations.

The Reinsurance Agreement will include the following among the limitations on the obligations of the Corporation.

(a) The Corporation may, at any time, suspend its obligation to accept additional liability from the company by providing written notice to that effect.

(b) The obligations of the Corporation under the Agreement are contingent upon the availability of appropriations.

(c) The Corporation will not reinsure any policy sold by the company to a producer after the date the company receives notice that the Corporation has determined that the producer is ineligible to receive Federal crop insurance.

##### § 400.79 Obligations of participating insurance company.

The Reinsurance Agreement will include the following among the obligations of the Company.

(a) The company shall follow all Corporation procedures in its administration of the crop insurance policies reinsured.

(b) The company shall make available to all eligible producers crop insurance for the crops and in the areas which are stated in its plan of operation which is approved by the Corporation.

(c) The company shall provide the Corporation, on forms approved by the Corporation, all information that the Corporation may deem relevant in the administration of the Agreement, including a list of all applicants refused coverage and all insured producers cancelled from insurance, along with the reason for such action, the crop program and the amount of coverage for each.

(d) The company shall utilize only loss adjustment procedures and methods that are approved by the Corporation.

(e) The company shall sell the policies covered under the Agreement through licensed agents or brokers who have successfully completed a training course approved by the Corporation.

(f) The company shall not discriminate against any employee, applicant for employment, insured or applicant for insurance because of race, color, religion, sex, age, handicap, or national origin.

##### § 400.80 Disputes.

All disputes arising under this Subpart and the Agreement entered into by the company and the Corporation must be submitted for decision to the Manager of the Corporation. The decision for the Manager shall be final unless the company requests reconsideration in writing within 30 days of the receipt of the decision. Any hearing provided by the Corporation will be of an informal nature and the rules of evidence will not apply. Pending final decision of the dispute, the company will proceed diligently with the performance of the Agreement, as required by the Corporation.



**§ 400.81 OMB control numbers.**

The information collection requirements contained in the Agreement, to which these operating procedures apply, have been approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Nos. 0563-0003 and 0563-0007.

Done in Washington, D.C., on March 25, 1985.

Peter F. Cole,  
Secretary, Federal Crop Insurance  
Corporation.

Dated: April 22, 1985.

Approved:

Edward Hews,  
Acting Manager.

[FR Doc. 10194 Filed 4-24-85; 11:13 am]

BILLING CODE 3410-05-M

**Commodity Credit Corporation****7 CFR Part 1421**

[Amdt. 4]

**Standards for Approval of  
Warehouses for Grain, Rice, Dry Edible  
Beans, and Seed**

**AGENCY:** Commodity Credit Corporation,  
USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This rule proposes to amend the regulations found at 7 CFR 1421.5551 *et seq.* relating to the Commodity Credit Corporation (CCC) Standards for Approval of Warehouses for Grain, Rice, Dry Edible Beans, and Seed. The proposed rule would: (1) Permit a parent company to submit a financial statement for a wholly-owned subsidiary; (2) permit warehousemen to submit financial statements on forms other than Form TW-51; (3) revise the references to CCC regulations governing suspension and debarment; (4) permit CCC to accept an irrevocable letter of credit on forms other than Form CCC-33A; (5) delete the use of a Certificate of Competency issued by the Small Business Administration for a warehouseman who is deficient in net worth; (6) delete certain references to the withdrawal of approval of warehouses by CCC; and (7) make certain other miscellaneous changes.

**DATE:** Comments must be received on or before May 28, 1985 in order to be assured of consideration.

**ADDRESS:** Interested persons are invited to send written comments to Paul W. King, Director, Warehouse Division, United States Department of Agriculture, Agricultural Stabilization

and Conservation Service, P.O. Box 2415, Washington, D.C. 20013; (202) 447-4018 or 447-7433.

**FOR FURTHER INFORMATION CONTACT:**

Lynda Flament, 202-447-7912,  
Warehouse Division, U.S. Department of Agriculture, Agricultural Stabilization and Conservation Service, P.O. Box 2415, Washington, D.C. 20013.

**SUPPLEMENTARY INFORMATION:** This proposed rule has been reviewed under USDA procedures established in accordance with Departmental Regulation 1512-1 and Executive Order 12291 and has been classified "not major." It has been determined that the provisions of this proposed rule will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local governments, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

It has been determined by an environmental evaluation that his action will have no significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

It has been determined that the Regulatory Flexibility Act is not applicable to this proposed rule since the Commodity Credit Corporation is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of rulemaking with respect to the subject matter of this rule.

This program/activity is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

The Commodity Credit Corporation (CCC) Charter Act (15 U.S.C. 714) provides authority for CCC to conduct a number of operations to stabilize, support, and protect farm income and prices. CCC is authorized to carry out such activities as making price support available with respect to various agricultural commodities, removing and disposing of surplus agricultural commodities, exporting or aiding in the exportation of agricultural commodities, and procuring agricultural commodities for sale both in the domestic market and abroad.

Section 4(h) of the CCC Charter Act provides that the Corporation shall not acquire real property in order to provide storage facilities for agricultural commodities, unless CCC determines that private facilities for the storage of such commodities are inadequate. Further, section 5 of the CCC Charter Act provides that, in carrying out the Corporation's purchasing and selling operations, and in the warehousing, transporting, processing, or handling of agricultural commodities, CCC is directed to use, to the maximum extent practicable, the usual and customary channels, facilities, and arrangements of trade and commerce.

Accordingly, CCC has set forth standards of approval which must be met by warehousemen before CCC will enter into storage agreements with such warehousemen for the storage of agricultural commodities which are owned by CCC or which are serving as collateral for price support loans made available by CCC.

CCC proposes to amend the following regulations which govern the Standards for Approval of Warehouses for Grain, Rice, Dry Edible Beans, and Seed (7 CFR 1421.5551 *et seq.*) in the manner described below.

Section 1421.5551(d)(2) of the regulations currently requires warehousemen to submit financial statements of Form TW-51 and permits a chain of warehouses owned and operated by a single business entity to submit only one financial statement. That form has been revised and is now form WA-51-2. Several warehousemen have complained that their independently prepared financial statements should satisfy CCC needs and they should not be required to incur the added expense and paperwork burden of submitting financial information on CCC's form. Also, several warehousemen whose warehouse facilities are wholly-owned and operated by a parent company have requested that the financial statement which is prepared for the parent company and which includes the combined financial position of the parent company and all subsidiaries be accepted by CCC. These warehousemen believe that to prepare a separate financial statement for each subsidiary warehouse is very costly and unnecessary. This proposed rule would permit warehousemen to submit financial statements to CCC on forms other than the WA-51-2 with the approval of the Director, Kansas City Commodity Office (KCCO), or the Director's designee. In addition, this proposed rule provides that a financial



statement from the parent company may be accepted by CCC in lieu of individual statements from each wholly-owned subsidiary if approved by the Director, KCCO, or the Director's designee.

Section 1421.5552(c) of the regulations currently provides that, in meeting the standards for approval, the warehouseman, officials and each of the supervisory employees of the warehouseman in charge of the warehouse must not be either suspended or debarred under CCC's suspension and debarment regulations, 7 CFR Part 1407. The Board of Directors of the Corporation has adopted, with limited reservations, the regulations implemented by the Department of Agriculture with respect to the suspension and debarment of individuals and firms contracting with CCC. The provisions of § 1421.5552(c) have been revised to merely reference the CCC suspension and debarment regulations. A conforming amendment has also been made in § 1421.5556(c)(2).

Section 1421.5553(e) of the regulations currently provides that CCC may accept an irrevocable letter of credit in lieu of the required amount of bond coverage if the issuing bank is a commercial bank insured by the Federal Deposit Insurance Corporation and the letter of credit is submitted to CCC on Form CCC-33A, "Irrevocable Letter of Credit". Several banks have objected to the use of Form CCC-33A and would prefer to use their own letter of credit form. This proposed rule would permit commercial banks to issue letters of credit on forms other than Form CCC-33A, provided that such forms are approved by the Director, KCCO, or the Director's designee.

Section 1421.5555(b) of the regulations currently provides that a Certificate of Competency issued by the Small Business Administration (SBA) for a warehouseman will be accepted by CCC for the purpose of establishing conformance by the warehouseman with certain of the Standards for Approval and the warehouseman will not be required to furnish bond coverage for any deficiency in net worth. The SBA has been reluctant to issue a Certificate of Competency to warehousemen since there is no guarantee that CCC-owned commodities will be stored with a warehouseman who has been issued a certificate. In fact, there have been no grain, rice, bean, or seed warehousemen approved with Certificate of Competency in the recent past.

Accordingly, it has been concluded that the provisions of § 1421.5555(b), which references the use of a Certificate of Competency, are not needed and this

proposed rule would delete that section accordingly.

Section 1421.5556 of the present regulations sets forth the procedures under which CCC approves or disapproves a warehouse for the purpose of storing commodities owned by CCC or pledged to CCC as price support loan collateral. These regulations also provide for the administrative appeal procedures which may be utilized by a warehouseman whose warehouse was not approved by CCC. In addition, § 1421.5556 sets forth the procedures and requirements involving the withdrawal of approval of a warehouse by CCC as a result of the failure of the warehouse to continue meeting the standards for approval or for the failure of the warehouseman to perform the contractual obligations specified in the CCC storage agreement. This proposed rule would delete any references in § 1421.5556 to the withdrawal of approval of warehouses by CCC since it is felt that these regulations should only relate to the approval, rather than the disapproval, of warehouses by CCC. The terms and conditions with respect to the continuing obligations of the warehouseman to meet the standards of approval and storage commitments will be set forth in the Storage Agreement entered into between the warehouseman and CCC.

Section 1421.5556(c)(1) has also been revised to provide that any request by a warehouseman for reconsideration of a determination by CCC that the warehouseman has failed to meet the Standards for Approval must be in writing. Previously, such a request for reconsideration could be made orally to the Director, KCCO, as well as in writing.

In addition to the foregoing, the following changes have been made: (1) Section 1421.5551(b) of the regulations has been amended to correct the mailing address for the Kansas City Commodity Office, and the table of contents has been revised; (2) section 1421.5558 has been revised to simplify the language and delete the current contract fee schedule since it is subject to change; and (3) a new § 1421.5559 has been added to include control numbers assigned by the Office of Management and Budget (OMB) under provisions of 44 U.S.C. Chapter 35 to information collection requirements.

#### List of Subjects in 7 CFR Part 1421

Grains, Loan programs, Agriculture, Oilseeds, Peanuts, Price support programs, Soybeans, Surety bonds, Tobacco, and Warehouses.

#### Proposed Rule

Accordingly, it is proposed that the regulations at 7 CFR Part 1421 be amended as follows:

1. The Authority citation to 7 CFR Part 1421, Subpart—Standards for Approval of Warehouses for Grain, Rice, Dry Edible Beans, and Seed is added to read as follows:

Authority: Secs. 4 and 5, 62 Stat. 1070, as amended; 1072, as amended (15 U.S.C. 714 b and c).

2. In Section 1421.5551, paragraphs (b) and (d)(2) (iv) and (v) are revised to read as follows:

#### § 1421.5551 General Statement and Administration.

(b) Copies of the CCC storage agreement and forms required for obtaining approval under this subpart may be obtained from the Kansas City Commodity Office, U.S. Department of Agriculture, P.O. Box 205, Kansas City, Missouri 64141 (hereinafter referred to as the "KCCO").

(d) \* \* \*

(2) \* \* \*

(iv) A current financial statement on Form WA-51-2, "Financial Statement", supported by such supplemental schedules as CCC may request. Financial statements may be submitted on forms other than Form WA-51-2 with approval of the Director, KCCO, or the Director's designee.

(v) Only one financial statement is required for a chain of warehouses owned or operated by a single business entity. If approved by the Director, KCCO, or the Director's designee, the financial statement of a parent company, which includes the financial position of a wholly-owned subsidiary, may be used to meet the CCC standards for approval for the wholly-owned subsidiary.

4. In Section 1421.5552, paragraph (c)(2) is revised to read as follows:

#### § 1421.5552 Basic standards.

(c) \* \* \*

(2) Be neither suspended nor debarred under applicable CCC suspension and debarment regulations.

5. In Section 1421.5553, paragraph (e) is revised to read as follows:

#### § 1421.5553 Bonding requirements for net worth.



(e) An irrevocable letter of credit may be accepted by CCC in lieu of the required amount of bond coverage provided that the issuing bank is a commercial bank insured by the Federal Deposit Insurance Corporation. Such standby letter of credit shall be on Form CCC-33A, "Irrevocable Letter of Credit", or on such other form as may be specifically approved by the Director, KCCO, or the Director's designee.

6. Section 1421.5555 is amended by deleting paragraph (b) and by redesignating paragraph (c) as paragraph (b).

7. Section 1421.5556 is revised to read as follows:

**§ 1421.5556 Approval of warehouses, requests for reconsideration.**

(a) CCC will approve a warehouse if it determines that the warehouse meets the standards set forth in this subpart. CCC will send a notice of approval to the warehouseman. Approval under this subpart, however, does not relieve the warehouseman of the responsibility for performing the warehouseman's obligations under any agreement with CCC or any other agency of the United States.

(b) Except as otherwise provided in this subpart:

(1) CCC will not approve the warehouse if CCC determines that the warehouse does not meet the standards set forth in this subpart, and

(2) CCC will send any notice of rejection of approval to the warehouseman. The notice will state the cause(s) for such action. Unless the warehouseman or any officials or supervisory employees of the warehouseman are suspended or debarred, CCC will approve the warehouse if the warehouseman establishes that the causes for CCC's rejection of approval have been remedied.

(c) If rejection of approval by CCC is due to the warehouseman's failure to meet the standards set forth:

(1) In § 1421.5552, other than the standard set forth in paragraph (c)(2) thereof, the warehouseman may, at any time after receiving notice of such action, request reconsideration of the action and present to the Director, KCCO, in writing, information in support of such request. The Director shall consider such information in making a determination and notify the warehouseman may, if dissatisfied with the Director's determination, obtain a review of the determination and an informal hearing thereon by filing an appeal with the Deputy Administrator, Commodity Operations, Agricultural Stabilization and Conservation Service

(hereinafter referred to as "ASCS"). The time for filing appeals, forms for requesting an appeal, nature of the informal hearing, determination and reopening of the hearing shall be as prescribed in the ASCS regulations governing appeals, 7 CFR Part 780. When appealing under such regulations, the warehouseman shall be considered as a "participant"; and

(2) In § 1421.5552(c)(2), the warehouseman's administrative appeal rights with respect to suspension and debarment shall be in accordance with applicable CCC regulations. After expiration of a period of suspension or debarment, a warehouseman may, at any time, apply for approval under this subpart.

7. Section 1421.5558 is revised to read as follows:

**§ 1421.5558 Contract fees.**

(a) Each warehouseman who has a non-Federally licensed grain or rice warehouse in States that do not have a Cooperative Agreement with CCC for warehouse Examinations must pay an annual contract fee to CCC for each such warehouse which is approved by CCC or for which CCC approval is sought as follows:

(1) A warehouseman who has an existing agreement with CCC for the storage or handling of CCC-owned commodities or commodities pledged to CCC as loan collateral must pay an annual contract fee for each warehouse approved under that agreement in advance of the renewal date of such agreement.

(2) A warehouseman who does not have an existing agreement with CCC for the storage and handling of CCC-owned commodities or commodities pledged to CCC as loan collateral but who desires such an agreement must pay a contract fee for each warehouse for which CCC approval is sought prior to the time that the agreement is approved by CCC.

(b) The amount of the contract fee shall be determined and announced annually in the Federal Register.

9. Section 1421.5559 is added to read as follows:

**§ 1421.5559 OMB control numbers assigned pursuant to Paperwork Reduction Act.**

The information collection requirements contained in this regulation (7 CFR Part 1421) have been approved by the Office of Management and Budget under provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Numbers 0560-0009, 0560-0036.

Signed at Washington, D.C., on April 23, 1985.

Everett Rank,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 85-10108 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-05-M

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

#### Specific Exemptions

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Nuclear Regulatory Commission is proposing to amend its regulations to clarify the standards that will be applied when it considers whether to grant exemptions from the regulatory requirements codified in 10 CFR Part 50.

**DATE:** Comment period expires May 28, 1985. Comments received after that date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before May 28, 1985.

**ADDRESSES:** Send Comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attn: Docketing and Service Branch. Hand deliver comments to: Room 1121, 1717 H Street, NW., Washington, D.C. between 8:15 a.m. and 5: p.m.

**FOR FURTHER INFORMATION CONTACT:** F. X. Cameron, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: 301-492-8689

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 50.12 of Chapter 1, Title 10 of the Code of Federal Regulations provides that the Commission may grant exemptions from the regulations in Part 50 that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Traditionally, this authority has been delegated by the Commission to its staff which determines whether exemptions are needed and justified. The Commission believes that it is not possible for its regulations to predict and accommodate every conceivable circumstance. Consequently, it has historically provided mechanisms to grant exemptions or waivers where application of the regulation would not serve the public interest and no undue



risk to the public health and safety would occur as a result of not requiring literal adherence to a particular requirement.

In several recent adjudicatory proceedings reviewed by the Commission, it has become evident that it would be desirable to attempt to state clearly the circumstances where the Commission believes that exemptions are warranted for the guidance of applicants, licensees, the staff and the public.

The Commission wishes to emphasize that it expects the intent of its regulations to be met and normally this requires conforming to the regulations as stated. The Commission recognizes, however, that there are circumstances where on balance it would not be equitable or in the public interest to require literal adherence to regulations particularly where to so require would not result in an improvement in overall safety or a reduction in risk to the public. The objective of the proposed rule is to identify the criteria to apply in such circumstances and to provide a means for considering the equities so that consistent regulatory decisions can be made concerning exemptions to Commission regulations.

The authority of an administrative agency to provide for exemptions from its regulations is well-established.<sup>1</sup> In *U.S. v. Allegheny-Ludlum Steel Corp.*, Justice Rehnquist stated that:

It is well established that an agency's authority to proceed in a complex area . . . by means of rules of general application entails a concomitant authority to provide exemptions procedures in order to allow for special circumstances. 406 U.S. 742, 755 (1972).

However, judicial decisions also reject the approach of granting exemptions indiscriminately. As described by Judge Leventhal in *WAIT Radio v. FCC*:

The agency may not act out of unbridled discretion or whim in granting waivers any more than in any other aspect of its regulatory function. 418 F.2d 1153, 1157 (D.C. Cir. 1969). See also, *Basic Media Ltd., v. FCC*, 559 F.2d 830, 833 (D.C. Cir. 1977); *Mary Carter Point Co. v. FCC*, 333 F.2d 654, 660 (5th Cir. 1964) (concurring opinion).

The courts have cited several permissible rationales for the granting of exemptions. In *U.S. v. Allegheny-Ludlum Steel Corp.*,<sup>supra</sup>, the Supreme Court cited "special circumstances" as a rationale for granting exemptions. In

*WAIT Radio*, the D.C. Circuit believed that an exemption or waiver provision might account for considerations of "hardship, equity, or more effective implementation of overall policy." *Supra.* at 1159. In *Basic Media, supra*, the D.C. Circuit stated that any rule of general applicability will involve particular cases of hardship for which an agency would grant an exemption. Similarly, in *Gulf Oil Corp. v. Hickey*, 435 F.2d 440 (D.C. Circuit 1970), the court found that a provision for adjustment in cases of extreme hardship is a meaningful component of a regulatory scheme. Another rationale was provided in *Industrial Broadcasting Co., v. FCC*, 437 F.2d 880 (D.C. Cir. 1970) where the court held that the desired flexibility in the regulatory process is maintained by requiring the agency to take a hard look at novel proposals, i.e., where the person seeking a waiver can demonstrate that his or her circumstances are substantially different from those which have been carefully considered in the rulemaking proceeding from which an exemption is desired.

In conformance with the principle that a means of granting relief from regulations should be provided, 10 CFR 50.12(a) of the Commission regulations provides that:

(a) The Commission may, upon application by any interested person or upon its own initiative grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. To obtain an exemption to Appendices C and H to this part, the requirements of paragraph 50.60(b) of this part must be met in addition to the requirements of this paragraph.

At this point, it should be noted that 10 CFR 50.12(b) establishes a separate exemption procedure to permit the carrying out of construction activities, normally prohibited by 10 CFR 50.10, prior to the issuance of a construction permit.<sup>2</sup> The § 50.12(b) procedures are

not of concern here and are left undisturbed by this proposed rulemaking.

In reviewing § 50.12(a) requests for exemptions, the focus of the NRC staff ("staff") has been on whether any undue risk would result from the granting of a particular exemption. This determination was, in general, the result of a qualitative engineering analysis of the purpose of the regulatory requirement and of the specific methods specified in the regulation for achieving the regulatory purpose. The staff would then compare the proposed method of operation to ensure that the regulatory purpose was satisfied and that the method to be used in a particular case was, under the particular circumstances before the staff, appropriate and technically sound as a method for accomplishing the regulatory purpose. In recent years when probabilistic quantitative assessment techniques have been available, these techniques, along with engineering judgment, have been used to ensure that the exemption involved was acceptable from a safety standpoint. In summary, the staff would evaluate an exemption request to determine if there was a justifiable reason for the proposed exemption and, in addition, whether adequate protection of the public health and safety would be maintained if the exemption were granted.

In addition, the staff viewed the Commission's regulatory framework as containing a reasonable amount of flexibility, with various requirements applicable only for certain modes of operation, and operation at certain times and power levels. For a typical power reactor under operating license review, the staff normally would recognize that, while the plant was ready for low power operation, power ascension or even initial full power operation, the plant might not fully comply with each and every NRC regulation. In these circumstances, "non-compliances" typically were dealt with by license conditions requiring completion of installation, testing, or further analyses before proceeding to a particular power level ("Prior to exceeding 5% power \* \* \*") or by a particular time ("By the first refueling outage \* \* \*"). The effect on safety of such temporary "non-compliances" was evaluated by the Staff and discussed and justified in the staff safety evaluation report or supplement thereto. In situations where the noncompliances would be corrected in a relatively short time and did not prevent a finding of adequate safety, the staff would condition the operating license so as to mandate that the

<sup>2</sup> For a thorough discussion of the application of 10 CFR 50.12(b), see, *In the Matter of United States Department of Energy, Project Management Corporation, Tennessee Valley Authority (Clinch River Breeder Reactor Plant) CLI-83-1*, 17 NRC 1 (1983). Note that 10 CFR 2.758(b) of the Commission's regulations allows a party to an adjudicatory proceeding involving an initial licensing decision to petition for a waiver or exemption from the application of a Commission regulation. The sole ground for such a waiver is that special circumstances in the particular proceeding are such that application of the regulation would not serve the purposes for which the regulation was adopted. Section 2.758(b) is also unaffected by this proposed rulemaking.

<sup>1</sup> See, *Allegheny-Ludlum Steel Corp. v. U.S.*, 406 U.S. 742, 755 (1972); *WAIT Radio v. FCC*, 418 F.2d 1153, (D.C. Cir. 1969); *Gulf Oil Corp. v. Hickey*, 435 F.2d 440, 447, (D.C. Cir. 1970); *Industrial Broadcasting Co. v. FCC*, 437 F.2d 880, 883 (D.C. Cir. 1970); *Basic Media Ltd. v. FCC*, 559 F.2d 830 (D.C. Cir. 1977).



requirements be met at a later time or before a particular power level rather than expressly consider or grant an exemption from the regulations for the period of operation prior to reaching the time or power level at which the deficiency was to be corrected. In issuing operating licenses, the staff only considered and explicitly granted exemptions in instances of long-term or permanent non-compliance with the regulations and where, of course, the staff could find that the standards for granting an exemption in 10 CFR 50.12(a) were satisfied. Note that the proposed rule, when it becomes effective, would eliminate the existing practice of granting temporary "non-compliances" without expressly granting an exemption under 50.12(a).

The Commission's recent decision on an exemption request for the Shoreham nuclear power plant,<sup>9</sup> represented a departure from past staff practice in the exemption area. In Shoreham, the Commission requested the applicant, in addressing the determinations to be made under the 10 CFR 50.12(a) exemption criteria, to include a discussion of:

1. The "exigent circumstances" that favor the granting of an exemption under 10 CFR 50.12(a) should it be able to demonstrate that, in spite of its noncompliance with GDC 17, the health and safety of the public would be protected.

2. Its basis for concluding that, at the power levels for which it seeks authorization to operate, operation would be as safe under the conditions proposed by it, as operation would have been with a fully qualified onsite A/C power source.

In the context of exemptions related to plant operations, these determinations regarding "exigent circumstances" and "as safe as" are not explicitly stated in 10 CFR 50.12(a). Although the Commission later specified that *Shoreham* was only to apply to the particular circumstances of that case, the decision did underscore the need to review existing Commission practice in the exemption area. The proposed rule is an attempt to fashion a comprehensive, consistent, practicable, and appropriate framework for reviewing exemption requests, based on past staff practice and on the Commission's concerns, as evidenced in the *Shoreham* decision and related discussions.

## II. The Proposed Rule

The proposed rule retains the existing criteria of § 50.12(a) in a slightly modified form, as general standards for

the granting of exemptions. Under proposed § 50.12(a)(1), the Commission may grant exemptions which:

are authorized by law, will not present an undue risk to the public health and safety, are consistent with the common defense and security, and are in the public interest.

As in the existing rule, an exemption must be "authorized by law." Apart from the very fact of granting the exemption relief itself, the granting of the exemption cannot be in violation of other applicable laws, such as the Atomic Energy Act, or the National Environmental Policy Act.

In a departure from the text of the existing rule, the proposed rule would require a finding that the exemption will not "present an undue risk to the public health and safety" and would be "consistent with the common defense and security." These criteria provide an explicit recognition of traditional staff practice in evaluating the safety implications of a particular exemption. It is anticipated that this evaluation will consider such factors as compensatory measures, length of time that the exemption will be in effect, and stage of plant operation (i.e., fuel loading, low power, full power, etc.). The Commission believes that the "not endanger" language in the current rule was never intended to embody any special standards for exemptions that differed from the statutory standards that licensing must provide adequate protection to the health and safety of the public and be in accord with the common defense and security. The "no undue risk" standard of the proposed rule is a refinement of the statutory standard that reflects current staff practice in the exemptions area.

As is currently required by § 50.12(a), the proposed rule would also require that the exemption be in the "public interest." However, in recognition of the Commission's decision in *Shoreham*, *supra*, the Commission wishes to explicitly state that the public interest determination will consist of a consideration of the special circumstances that justify the exemption. Apart from those related conditions set forth in proposed § 50.12(a)(2), discussed *infra*, that are specific applications of "special circumstances," this determination would be confined to the consideration of the equities of the situation, similar to those cited in the *Shoreham* decision, including the stage of the facility's life, any financial or economic hardships, any unusual difficulties in complying with the regulation, any internal inconsistencies in the regulation, the applicant's good faith effort to comply

with the regulation from which the exemption is sought, the public interest in adherence to the Commission's regulations, and the safety issues involved.

The Commission notes that because the criteria in proposed § 50.12(a)(1) will now include consideration of hardships or unusual difficulties, as well as the level of safety, it is deleting the provision from existing § 50.12(a) on additional requirements for exemptions from the fracture toughness requirements of 10 CFR Part 50, Appendices G and H. A corresponding deletion has been made to 10 CFR 50.60.(b).

In addition to the general standards of proposed § 50.12(a)(1) the Commission is proposing to add a new § 50.12(a)(2), which would require that one of several conditions exist before an exemption could be granted. The Commission believes that these conditions represent situations in which it would be reasonable to grant an exemption, provided that the general standards of § 50.12(a)(1) are also met. These conditions were selected on the basis of exemption criteria that have been noted by the courts with approval (special circumstances, hardship, equity, more effective implementation of overall policy, circumstances substantially different from those considered in the rulemaking proceeding) and on the basis of examples from past Commission exemption practice where the circumstances underlying the exemption appeared to be relevant and appropriate for exemption relief.<sup>4</sup> The Commission would emphasize that the conditions in proposed § 50.12(a)(2) constitute a specific application of either the safety criterion or the public interest (special circumstances) criterion stated in the general standards of proposed § 50.12(a)(1). Although an exemption request may satisfy one of the conditions in proposed § 50.12(a)(2), the general criteria in proposed § 50.12(a)(1) must also be satisfied. For example, proposed § 50.12(a)(2)(iii) establishes a condition that "alternative or compensatory means exist to achieve the underlying purpose of the rule." Although the exemption request may satisfy this specific condition, it must also satisfy the general public interest

<sup>9</sup> In the Matter of Long Island Lighting Company (Shoreham Nuclear Power Station, Unit 1), CLI-84-8, slip op., (May 16, 1984) (hereinafter "Shoreham").

<sup>4</sup> As noted by the D.C. Circuit in *WAT Radio v. FCC*, 418 F.2d 1153, 1159, (D.C. Cir. 1969): Sound administrative procedures contemplates waivers, or exemptions granted only pursuant to a relevant standard . . . best expressed in a rule that obviates discriminatory approaches . . . The process viewed as a whole leads to a general rule, and limited waivers or exemptions granted pursuant to an appropriate general standard.



(special circumstances) criterion of proposed § 50.12(a)(1) to justify the granting of the exemption. The Commission's objective in establishing the conditions of § 50.12(a)(2) is to impose limits on the type of exemption requests that can be granted. The addition of § 50.12(a)(2) is intended to reaffirm and strengthen the existing NRC policy and practice of evaluating and granting exemptions in a judicious and discriminating manner.

Proposed § 50.12(a)(2) would require that one of the following be satisfied before an exemption could be granted:

- Application of the regulation in the particular circumstances would be in conflict with other rules of the Commission; or

- Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or

- Alternative or compensatory means exist to achieve the underlying purpose of the regulation;

- The exemption would result in an overall benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption; or

- Application of the regulation would result in treatment of the particular applicant or licensee in a manner substantially different than other similarly situated applicants or licensees; or

- The exemption would provide only temporary relief from the applicable regulation; or

- There is present any other material circumstance not considered when the regulation was adopted.

Proposed § 50.12(a)(2)(i) would address those situations where application of a regulation in a particular circumstance would be in conflict with other rules or the Commission. This provision is designed for those rare situations where an applicant or licensee would be in the anomalous position of satisfying two or more conflicting requirements.

Proposed § 50.12(a)(2)(ii) would address those situations where application of the regulations in the particular circumstances is not necessary to achieve, or would not serve, the underlying purpose of the rule. This would include those situations considered in requests for exemptions under 10 CFR 2.758(b), where circumstances peculiar to that case, as opposed to any alleged generic inadequacy of the regulation, may result in the frustration of the underlying purpose of the rule. For example, see, *In the Matter of Pacific Gas and Electric*

*Company* (Diablo Canyon Nuclear Power Plant, Units 1 and 2), ALAB-653, 16 NRC 55 (1981); *In the Matter of Metropolitan Edison Company* (Three Mile Island Nuclear Station, Unit No. 1), CLI-80-16, 11 NRC 674 (1980); *In the Matter of Duke Power Company* (Catawba Nuclear Station, Units 1 and 2), CLI-79-9, 2 NRC 180 (1985).

Proposed § 50.12(a)(2)(iii) addresses situations where alternative or compensatory means exist to achieve the underlying purpose of the regulation. This would allow an exemption request to be considered where it could be shown that satisfactory alternative or compensatory mechanisms exist to achieve the regulatory objective. It must be understood here that the underlying purpose of the rule should be something more specific than achieving adequate safety protection. Otherwise all of the safety requirements in 10 CFR Part 50 become subject to open litigation, and the exemption process becomes open ended. Rather, the specific objective of the regulation must be ascertained from the rule itself or the underlying rulemaking proceeding (for example, the specific purpose of 10 CFR 50.46 would be assuring a coolable core during and after postulated loss-of-coolant accidents).

Proposed § 50.12(a)(2)(iv) would address situations where the exemption would result in an overall benefit to health and safety. This provision would focus on those circumstances where, on balance, the exemption would actually result in a net increase in overall safety or quality of plant operations.

Proposed § 50.12(a)(2)(v) would address those situations where the application of the regulation would result in treating a particular applicant or licensee in a manner substantially different than other similarly situated applicants or licensees. This is intended to provide equitable treatment to applicants or licensees who, because of some unusual circumstance, are affected in a manner different than that of other similarly situated licensees or applicants. For example, see *In the Matter of Duke Power Company* (Catawba Nuclear Station, Units 1 and 2), CLI-79-9, 2 NRC 180 (1985).

Proposed § 50.12(a)(2)(iv) establishes a condition where the exemption would provide only temporary relief from the applicable regulation. This would cover the so-called "scheduler" exemption where the relief sought is limited to a specific amount of time or until a specific event occurs. The applicant's good faith efforts to comply with the required schedule would be one of the factors considered under § 50.12(a)(1) in

determining whether to grant the exemption.

Proposed § 50.12(a)(2)(vii) establishes a category of any other material circumstances not considered when the regulation was adopted. Although the Commission believes that the conditions in proposed § 50.12(a)(2)(i) through (vi) will cover most requests in which an exemption could reasonably be granted, proposed § 50.12(a)(2)(vii) recognizes that there may be circumstances, which could not have been foreseen in developing the conditions in proposed § 50.12(a)(2)(i) through (vi), in which it would be equitable to provide relief from the regulations. In these cases, after documentation of a material circumstance not considered when the regulation was adopted and meeting the general criteria, including "no undue risk", in proposed § 50.12(a)(1), an exemption could issue. However, this provision would also require the Executive Director for Operations to consult with the Commission before the exemption could be granted.

The Commission would once again emphasize that although one of the above provisions of proposed § 50.12(a)(2) may be satisfied, the exemption request must still be evaluated in the overall context of the general standards in § 50.12(a)(1). It is conceivable that one of the conditions in § 50.12(a)(2) will be satisfied, but the general standards of § 50.12(a)(1) cannot be met.

The Commission directs the staff to utilize existing staff practice, pre-*Shoreham*, in evaluating exemptions, pending the effective date of this rulemaking.

#### Separate Views of Commissioner Asselstine

Commissioner Asselstine would like comments on the following proposed rule as an alternative to that proposed by the Commission:

#### Section 50.12 Specific exemptions.

(a)(1) The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part.

(2) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever:

(i) compliance with the regulations would be inconsistent with some other Commission requirement;

(ii) compliance with the regulation would decrease overall facility safety, or would not achieve or not be necessary to achieve the purpose of the regulation;



(iii) compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated;

(iv) a compliance issue is raised late in the licensing review that cannot be fully resolved in a timely fashion despite good faith efforts;

(v) compliance would result in applicant or licensee being treated in a manner significantly different from others similarly situated; or

(vi) there is present any other material circumstance not considered when the regulation was adopted.

(3) No exemption will be granted unless the Commission finds that it would be authorized by law and would be in accord with the common defense and security, and that there would be no undue risk to the health and safety of the public.

#### Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment. The proposed rule modifies the criteria for the consideration of exemption requests under 10 CFR Part 50. The adoption of such criteria does not have an environmental effect in and of itself. The potential environmental impact of a specific exemption will be evaluated at that time, as appropriate.

#### Paperwork Reduction Act

This proposed rule does not contain a new or amended information collection requirement subject to Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011.

#### Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the analysis may be obtained from: F.X. Cameron, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-8689.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

#### Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule, if adopted, will not have a significant economic impact upon a substantial number of small entities. The proposed rule primarily affects commercial power reactor licensees and license applicants, none of whom constitute a "small entity."

#### List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 50.

#### PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

**Authority:** Secs. 103, 104, 161, 162, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1246 as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2952 (42 U.S.C. 5851). Sections 50.57(d), 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10(b) and (c) and 50.54 are issued under sec. 161, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 181o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 50.12, paragraph (a) is revised to read as follows:

#### § 50.12 Specific exemptions.

(a) The Commission may, upon application by an interested person or upon its own initiative grant exemptions from the requirements of the regulations of this part, which—

(1) Are authorized by law, will not present an undue risk to the public health and safety, are consistent with the common defense and security, are in the public interest, and

(2) Meet one of the following—

(i) Application of the regulation in the particular circumstances would be in conflict with other rules of the Commission; or

(ii) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or

(iii) Alternative or compensatory means exist to achieve the underlying purpose of the regulation; or

(iv) The exemption would result in an overall benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption; or

(v) Application of the regulation would result in treatment of the particular applicant or licensee in a manner substantially different than other similarly situated applicants or licensees; or

(vi) The exemption would provide only temporary relief from the applicable regulation; or

(vii) There is present any other material circumstance not considered when the regulation was adopted. If such condition is relied on exclusively for satisfying paragraph (a)(2) of this section, the exemption shall not be granted until the Executive Director for Operations has consulted with the Commission.

3. In § 50.60, paragraph (b) is revised to read as follows:

**§ 50.60 Acceptance criteria for fracture prevention measures for lightwater nuclear power reactors for normal operation.**

(b) Proposed alternatives to the described requirements in Appendices G and H of this part or portions thereof may be used when an exemption is granted by the Commission under § 50.12

Dated at Washington, D.C., this 23rd day of April, 1985.



Nuclear Regulatory Commission.

John C. Hoyle,

Assistant Secretary of the Commission.

[FR Doc. 85-10186 Filed 4-25-85; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 85-CE-11-AD]

**Airworthiness Directives; Fairchild Aircraft Corporation Models SA226-T, SA226-AT, SA226-T(B), SA226-TC, SA227-AC, SA227-AT and SA227-TT Airplanes**

**AGENCY:** Federal Aviation Administration, (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This amendment proposes to adopt a new Airworthiness Directive (AD) that would require additional inspection and recalibration of certain components critical to the Stall Avoidance System (SAS) on Fairchild Aircraft Corporation Models SA226-T, SA226-AT, SA226-T(B), SA226-TC, SA227-AC, SA227-AT and SA227-TT airplanes. Instances have occurred involving unwarranted actuation of the SAS control stick pusher mechanism at low altitudes. The proposed AD will assure proper operation of the SAS and the stall warning horn, and preclude loss of control due to an unwarranted actuation of the SAS.

**DATE:** Comments must be received on or before July 1, 1985.

**ADDRESSES:** Send comments on the proposal in duplicate to the FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 85-CE-11-AD, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106. The service bulletins applicable to this AD may be obtained from the Fairchild Aircraft Corporation, Post Office Box 32486, San Antonio, Texas 78284.

#### FOR FURTHER INFORMATION

**CONTACT:** Mr. Sam Lovell, Airplane Certification Branch, ASW-150, Southwest Region, FAA, Fort Worth, Texas 76101; Telephone (817) 877-2448.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such

written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Director before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available both before and after the closing date for comments in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

#### Availability of NPRMs

Any persons may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Central Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 85-CE-11-AD, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

#### Discussion

The National Transportation Safety Board (NTSB) issued a Safety Recommendation (A-84-66) as a result of investigating one incident and receiving a report of another incident involving an unwarranted actuation of the SAS on certain Fairchild Model SA226 and SA227 airplanes. They recommended the FAA review the design, the installation, and the maintenance requirements for the SAS to verify system reliability and maintainability and take action as needed to preclude unwarranted actuation of the system that could present hazards to the airplane.

There are two systems presently being used on the above airplanes, the Rosemount and Conrac Systems. The Rosemount system was used in the earlier production airplanes and was replaced in later production airplanes by the Conrac system.

There have been 16 reports of unwarranted actuation of the SAS over a 5-year period. An additional 133 Malfunction of Defect (M or D) Reports were filed reporting various malfunctions with the SAS system. The majority of the 149 reports were a result of a lack of calibration of critical system components. In addition, proper

operation of the stall warning horn is dependent upon a properly calibrated SAS system. Should such an unwarranted actuation occur during takeoff or landing, where the airplane is at a low altitude, an accident or incident could result.

An evaluation of the design, installation, maintenance, and field data regarding these systems disclosed that lack of calibration may have caused the majority of the problems experienced in the field. An established periodic inspection and calibration procedure could have prevented many of the problems that were reported.

Since the condition described herein is likely to exist or develop in other Fairchild Models SA226 and SA227 airplanes, the AD would require inspection and modification of the SAS in accordance with existing manufacturer's bulletins.

The FAA has determined that this proposed regulation involves approximately 582 airplanes. The estimated average cost of compliance with one cycle of the A is \$970 per airplane. This cost precludes the proposed AD from having a significant economic impact on any small entity under the criteria of the Regulatory Flexibility Act. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); (3) does not warrant preparation of a Regulatory evaluation as the anticipated impact is so minimal; and (4) if promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption "ADDRESSES".

#### List of Subjects in 14 CFR 39

Air transportation, Aviation safety, Aircraft, Safety.

#### The Proposed Amendment

#### PART 39—[AMENDED]

Accordingly, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) by adding the following new AD:



## § 39.13 [Amended]

Fairchild Aircraft Corporation: Applies to Models SA226-T (S/N T201 thru T275, T277 thru T291), SA 226-AT (S/N AT001 thru AT 419, AT003E, AT038E, AT062E, AT064E), SA226-TC (S/N TC201 thru TC419, TC208E, TC211E, TC211EE, TC211EEE, TC211EEEE, TC222E, TC227E, TC228E, TC229E, TC234E, TC237E, TC238E, TC239E, TC331E, TC334E), SA226-T(B) (S/N T(B)276, T(B)292 thru T(B)417, T(B)303E), SA227-AC (S/N AC406, AC415, AC416, AC420 thru AC601, AC603), SA227-TT (S/N TT421 thru TT541), SA227-AT, (S/N AT423 thru AT585) airplanes certificated in any category.

Compliance: Required within 100 hours time-in-service after the effective date of this AD unless previously accomplished and thereafter as indicated below:

To assure proper operation of the Stall Avoidance System (SAS) system, accomplish the following:

(a) Except as noted in paragraph (b) of this AD, modify and/or inspect the applicable airplanes in accordance with the manufacturer's service bulletins, at the initial and repetitive time-in-service intervals, as specified for the model and serial numbered airplanes, set forth in Table 1 below:

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Table 1

Model	Serial Number	Fairchild Service Bulletin	Compliance Interval Hrs - Time in Service
SA226-T	T201 thru T275, T277 thru T291	226-A27-024	one time only
		226-A27-028	one time only
		226-27-038	
		Para. 2.A	200
SA226-AT	AT001 thru AT073, AT093E, AT038E, AT052E, AT064E	Para. 2.B	500
		Para. 2.C	800
		226-A27-024	one time only
		226-27-038	
SA226-TU	AT074 thru AT419	226-27-038	
		Para. 2.A	200
		Para. 2.B	500
		Para. 2.C	800
SA226-TT	TC201 thru TC314, TC206E, TC211E, TC211EE, TC211EEE, TC222E, TC227E, TC228E, TC229E, TC234E, TC237E, TC238E, TC239E	226-27-038	
		Para. 2.A	200
		Para. 2.B	500
		Para. 2.C	800
SA227-AT	AT423 thru AT549	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500
SA227-TT	TT421 thru TT526, TT528, TT530 thru TT534	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500
SA227-TU	TC201 thru TC314, TC206E, TC211E, TC211EE, TC211EEE, TC222E, TC227E, TC228E, TC229E, TC234E, TC237E, TC238E, TC239E	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500
SA227-AT	AT423 thru AT549	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500
SA227-TT	TT421 thru TT526, TT528, TT530 thru TT534	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500
SA227-TU	TC201 thru TC314, TC206E, TC211E, TC211EE, TC211EEE, TC222E, TC227E, TC228E, TC229E, TC234E, TC237E, TC238E, TC239E	227-27-004	one time only
		227-27-006	
		Para. 2.A	200
		Para. 2.B	500

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(b) Modify and/or inspect those Model SA226 and SA227 series airplanes which are equipped with the Conrac SAS system (per

STC 4725SW) in accordance with Table 2 below:

Table 2

Model	Fairchild Service Bulletin	Compliance Interval Hrs - Time in Service
Any applicable Model SA226 and SA227 airplanes incorporating STC 4725SW	226-27-037	
		Para. 2A 200
		Para. 2B 1200
		Para. 2C 2000

**Note. #1:** The current issue date and subject matter of the Service Bulletins specified in Table 1 are as follows:

- (1) 226-A27-024—"Flight controls-Elevator", dated 11/13/79.
- (2) 226-A27-028—"Flight controls-Rudder and Elevator", dated 12/11/80.
- (3) 226-A27-033—"Flight controls-Elevator", dated 12/03/82, Revised 01/06/83.
- (4) 227-A27-004—"Flight controls-Elevators", dated 12/03/82, Revised 01/06/83.
- (5) 226-27-037—"Conrac SAS System-Inspection and Recalibration", dated 02/15/85.
- (6) 226-27-038—"Rosemount SAS System-Inspection and Recalibration", dated 02/15/85.
- (7) 227-27-006—"Conrac SAS System-Inspection and Recalibrations", dated 02/15/85.

(c) An equivalent method of compliance with this AD may be used if approved by the Manager, Airplane Certification Branch, ASW-150, FAA Southwest Regional Office, Fort Worth, Texas 76101

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and Section 11.85 of the Federal Aviation Regulations (14 CFR 11.85))

Issued in Kansas City, Missouri, on April 15, 1985.

Murray E. Smith,

Director, Central Region.

[FR Doc. 85-10133 Filed 4-25-85; 8:45 am]

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#### 14 CFR Part 39

[Docket No. 85-ANE-2]

**Airworthiness Directives: Rolls-Royce Limited, Dart Model 542-4, 542-4K, 542-10, 542-10J, and 542-10K Turboprop Engines**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This notice proposes to amend an existing airworthiness directive (AD) applicable to Rolls-Royce Dart Model 542-4, 542-4K, 542-10, 542-10J, and 542-10K engines, by exempting certain propeller shafts from repetitive inspections, requiring the inspection of additional serial numbered propeller shafts and incorporating other minor editorial changes. This proposed amendment is needed to align the requirements of the AD with the current revision of the Rolls-Royce service bulletin (SB).

**DATE:** Comments must be received on or before July 5, 1985.

**ADDRESSES:** Comments on the proposal may be mailed in duplicate to: Federal Aviation Administration, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 85-ANE-2, 12 New England Executive Park, Burlington, Massachusetts 01803 or delivered in duplicate to Room Number 311 at the above address.

Comments delivered must be marked: Docket Number 85-ANE-2.

Comments may be examined at the New England Regional Office, Office of the Regional Counsel, Room Number 311, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday, except Federal holidays.

The applicable SBs may be obtained from Rolls-Royce Limited, Manager—Dart Service, East Kilbride, Glasgow G74 4PY, Scotland.

Copies of the SBs are contained in Rules Docket Number 85-ANE-2 in Office of the Regional Counsel, New England Region, Federal Aviation Administration, 12 New England

Executive Park, Burlington, Massachusetts 01803.

**FOR FURTHER INFORMATION CONTACT:** Kenneth W. Steeves, General Aviation Engine Branch, ANE-142, Engine Certification Office, Aircraft Certification Division, FAA, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7097.

#### SUPPLEMENTARY INFORMATION:

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Director before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available for examination in the Rules Docket, both before and after the closing date for comments, at the address given above. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 85-ANE-2." The postcard will be date/time stamped and returned to the commenter.

The FAA has determined that (1) propeller shafts marked "CU" have shown a complete absence of defects and consequently, no longer require repetitive in-service inspections at 1,200 hour intervals, (2) additional propeller shaft serial numbers which are shown in the current revision of Rolls-Royce SB Da72-367 should be included in the AD, and (3) minor editorial changes should be incorporated.

Therefore, the proposed amendment amends the existing AD as follows:

(a) Allows propeller shafts marked "CU" to be exempt from the repetitive in-service inspection requirements.

(b) Includes the additional serial numbered propeller shafts which are listed in the current revision of the SB.



(c) Incorporates minor editorial changes.

### Conclusion

The FAA has determined that this proposed regulation will be less burdensome on the operators. Even though this proposed AD includes additional serial number propeller shafts it is believed that, if any of these shafts are in the United States, they have been inspected. In addition, the elimination of the repetitive inspection will reduce the cost of this AD for each affected engine by \$400 per year. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); (3) does not warrant preparation of a regulatory evaluation as there is no anticipated impact; and (4) if promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety, Incorporation by reference.

#### The Proposed Amendment

Accordingly, the FAA proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) by amending Amendment 39-1119, AD 70-25-06 to read as follows:

**Rolls-Royce Limited:** Applies to Rolls-Royce Dart Models 542-4, 542-4K, 542-10, 542-10J, and 542-10K engines.

Compliance is required as indicated, unless already accomplished.

To prevent cracking and subsequent failure of the engine propeller shaft and damage to the coarse pitch oil line due to material inclusions in that part of the shaft between the annulus gear support diaphragms, accomplish the following:

(a) For all airplanes with Rolls-Royce Dart Models 542-4, 542-4K, 542-10, 542-10J, and 542-10K engines installed except those having engine propeller shafts installed which have been supplied by Rolls-Royce with "CU" marked on the front end of the shaft, or in which each engine propeller shaft has been overhauled (including ultrasonic inspection for cracks and material inclusions) in accordance with Rolls-Royce Dart Overhaul Manual O-Da10-AC and identified with "CU" marked on the front end of the shaft, and which are not listed in Appendix A and B of Rolls-Royce SBs Da72-367, Revision 3, dated June 2, 1978, within the next 50 hours' time in service after the effective date of this AD, install the following placard in clear view of the pilot and as close to the R.P.M. indicators as practicable: "In the event of abnormal, short duration R.P.M. increase (500-600 R.P.M.) accompanied by a drop in TGT and torque pressure at a fixed power setting, immediately feather affected

propeller per Aircraft Flight Manual feathering instructions."

(b) For engines which have been feathered in accordance with the placard in paragraph (a), before further flight, overhaul the engine propeller shaft (including ultrasonic inspection) in accordance with Rolls-Royce Dart Overhaul Manual O-Da10-AC to determine whether material inclusions or cracks exist in the part of the engine propeller shaft between the annulus gear support diaphragms, and whether the propeller coarse pitch oil line has been damaged. If material inclusions or cracks in the propeller shaft or damage to the propeller coarse pitch oil line are found, before further flight replace the cracked propeller shaft and damaged propeller coarse pitch oil line with an approved serviceable part.

(c) For all engines having propeller shafts with 1,200 or more hours' time in service on the effective date of this AD, within the next 450 hours' time in service and thereafter at intervals not to exceed 1,200 hours' time in service since the last inspection, inspect each engine propeller shaft (including ultrasonic inspection) in accordance with Rolls-Royce SB Da72-367. If material inclusions or cracks are detected during any inspection, before further flight replace the engine propeller shaft with an approved serviceable part.

(d) For all engines having propeller shafts with less than 1,200 hours' time in service on the effective date of this AD, within a total of 1,650 hours' time in service, and thereafter at intervals not to exceed 1,200 hours' time in service since the last inspection, inspect each engine propeller shaft (including ultrasonic inspection) in accordance with Rolls-Royce SB Da72-367. If material inclusions or cracks are detected during any inspection, before further flight replace the engine propeller shaft with an approved serviceable part.

(e) For all engines the repetitive in-service inspections required by paragraphs (c) and (d) may be discontinued when propeller shaft are installed which have been supplied by Rolls-Royce with "CU" marked on the front end of the shaft, or which have been overhauled (including ultrasonic inspection for cracks and material inclusions) in accordance with Rolls-Royce Dart Overhaul Manual O-Da10-AC and identified with "CU" marked on the front end of the shaft.

(f) For all engines with propeller shafts installed bearing the serial numbers listed in Appendix A and B of Rolls-Royce SB Da72-367, Revision 3, the placard required by paragraph (a) may not be removed.

(g) For all engines with propeller shafts installed bearing the serial number listed in Appendix A and B of Rolls-Royce SB Da72-367, Revision 3, the propeller shafts must be inspected at engine overhaul per the procedures described in paragraph 4B of Rolls-Royce SB Da72-367, Revision 3.

Upon request, an equivalent means of compliance may be approved by the Manager, Engine Certification Office, Aircraft Certification Division, New England Region, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803.

This proposed amendment will amend AD 70-25-06 Amendment 39-1119.

The FAA will request the permission of the Federal Register to incorporate by reference the manufacturer's SB identified and described in this document.

(Sec. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) [Revised, Pub. L. 97-449, January 12, 1983]; 14 CFR 11.85)

Issued in Burlington, Massachusetts, on April 16, 1985.

Robert E. Whittington,

Director, New England Region.

[FR Doc. 85-10134 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-13-M

### Federal Highway Administration

#### 23 CFR Parts 625 and 655

[FHWA Docket No. 85-18]

#### National Standards for Traffic Control Devices; Manual on Uniform Traffic Control Devices; Standards for Performance of Retroreflective Traffic Control Devices; Request for Comments

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Advance notice of proposed amendments to the manual on uniform traffic control devices; request for comments.

**SUMMARY:** The FHWA is inviting comments on a petition from the Center for Auto Safety (CAS) to initiate rulemaking consideration on the issue of standards for retroreflective illumination of traffic control devices. If adopted, these standards could be incorporated into the Manual on Uniform Traffic Control Devices (MUTCD). The MUTCD is incorporated by reference in the design standards for Federal-aid highways found in Part 625 of Title 23, Code of Federal Regulations (CFR). It is also recognized in 23 CFR Part 655 as the national standard for traffic control devices on all public roads.

**DATE:** Comments must be received on or before February 15, 1986.

**ADDRESS:** Submit written comments, preferably in triplicate, to FHWA Docket No. 85-18, Federal Highway Administration, Room 4205, HHC-10, 400 Seventh Street SW., Washington, D.C. 20590. All comments received will be available for examination at the above address between 7:45 a.m. and 4:15 p.m. e.t., Monday through Friday, those desiring notification of receipt of comments must include a self-addressed, stamped postcard. The



MUTCD is available for inspection and copying as prescribed in 49 CFR Part 7, Appendix D. It may be purchased for \$30.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 050-001-81001-8.

**FOR FURTHER INFORMATION CONTACT:** Mr. Philip O. Russell, Office of Traffic Operations, (202) 426-0411, or Mr. Michael J. Laska, Office of the Chief Counsel, 426-0762, 400 Seventh Street SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The FHWA both receives and initiates requests for amendments to the MUTCD. The MUTCD presents traffic control device (TCD) standards for all streets and highways open to public travel regardless of type or class or the governmental agency having jurisdiction.

The MUTCD fulfills a statutory responsibility imposed on the Secretary of Transportation in sections 109(b), 109(d), and 402(a) of Title 23 of the U.S.C. and delegated to the Federal Highway Administrator in 49 CFR 1.48 (b), (c), and (n). Generally, 23 U.S.C. 109 authorizes the Secretary to develop, approve, and apply standards for the construction of highways in which Federal funds participate. Section 109(b) calls for standards for the Interstate System to be applied "uniformly throughout the States." Section 109(d) directs the secretary to approve only such standards for "the location, form, and character" of signs, signals, and markings on Federal-aid highways "as will promote the safe and efficient utilization of the highways." Section 402(a) authorizes the Secretary to promulgate uniform national standards relating to "highway design and maintenance (including lighting, markings, and surface treatment), traffic control, vehicle codes and laws, surveillance of traffic," etc., for use on all public roads.

This advance notice is being issued so that interested persons and/or organizations may have the opportunity to participate in the consideration of this request for amendments to the MUTCD. Based upon comments received in response to this advance notice and upon its own experience, the FHWA may prepare a notice of proposed amendments. Any final amendments which result from that action will be published in the *Federal Register* and incorporated by reference in the Code of Federal Regulation.

The basic requirements for highway signs and pavement markings are that

they be legible and understood in time to permit a proper response. This means high visibility lettering or symbols of adequate size, and a short, accurate legend for driver comprehension at highway speed. Standard colors and shapes are specified so that special classes of traffic signs can be promptly recognized. Simplicity and uniformity in color, shape, position, and application are stressed throughout the MUTCD. The MUTCD presently provides that: (a) Regulatory and warning signs, unless excepted in the standards covering a particular sign or group of signs, shall be retroreflectorized or illuminated to show the same shape and color both by day and night, (b) pavement markings, which must be visible at night, shall be retroreflectorized unless ambient illumination assures adequate visibility, and (c) all pavement markings on Interstate highways shall be retroreflectorized.

The MUTCD contains no minimum initial or maintained retroreflective requirements for retroreflective traffic signs, pavement markings, or other traffic control devices. Minimum initial retroreflective requirements for new sheeting materials do exist. They are contained in General Services Administration's (GSA) Federal Specifications L-S-300C<sup>1</sup> and in "Standard Specifications for Construction of Roads and Bridges on Federal Highway Projects FP-79"<sup>2</sup> (FP-79) U.S. DOT FHWA. The FP-79 is issued primarily for use in the construction of roads and bridges on Federal highway projects under the direct supervision of the FHWA. The State and local highway agencies have direct supervision of their respective systems including the Federal-aid highway systems and, therefore, are not bound by the FP-79. Many State and local highway agencies have elected to use either the GSA or the FP-79 specification for procurement of sign sheeting material. The FP-79 also contains minimum maintained retroreflective intensity specifications for sheeting materials in construction and maintenance zones. The FHWA is not aware of any State or highway agency that has adopted these standards.

The CAS petition acknowledges that the MUTCD sets forth standards for size, shape, and color as well as legend

size and spacing for traffic control devices. However, the petition contends that the range of legally licensable drivers is not accommodated by the traffic control devices allowed in the MUTCD with respect to nighttime conspicuity dependent upon retroreflective illumination.

Copies of the CAS petition will be distributed to everyone currently appearing on the FHWA mailing list for MUTCD matters. Those wishing to be added to the mailing list or receive a copy of the petition should write to FHWA, Office of Traffic Operations, HTO-21, 400 Seventh Street SW., Washington, D.C. 20590.

#### Discussion of Problem

In the mid-1970's, approximately 55 percent of all vehicle deaths were reported to have occurred during the hours of darkness. By the early 1980's, the proportion of fatalities occurring at night had increased steadily to about 60 percent. Given the facts that hours of darkness constitute only about 40 percent of a 24-hour day and only about 25 percent of all travel occurs during this same period, nighttime accidents are over-represented in accident statistics. The night fatality rate is more than three times that of the daytime rate. The rural driver has a significantly greater nighttime risk than the driver in urban areas when compared on the basis of relative exposure (per vehicle miles of travel). Approximately two-thirds of nighttime fatalities occur on unlighted roadways mainly in rural areas. The proportion of single vehicle fatalities occurring at night has increased from 62 to 68 percent between 1975 and 1982.

It is generally recognized that a single causal factor cannot be assigned to night accidents. A driver's night vision characteristics and a lack of adequate visual guidance information are significant factors in the greater accident and fatality rates at night. Fatigue, intoxication, inclement weather, higher speeds of travels on some roadways, and other factors all contribute to the hazards of night driving. For example, accident risks are considerably greater on wet pavements at night than on dry pavements. The problem is even more extreme for operation on wet roads with control of access. The risk of an accident under night, wet conditions on a freeway appears to be about 10 to 15 times greater than that during dry, daytime conditions.

All of the above mentioned factors are made worse by poor visibility. The great majority of information that the road user requires to effectively carry out

<sup>1</sup> This document is available for inspection and copying at the Federal Highway Administration, Office of Traffic Operations, HTO-21, Room 3419, 400 7th Street SW., Washington, D.C. 20590.

<sup>2</sup> This document is available for inspection and copying at the Federal Highway Administration, Office of Traffic Operations, HTO-21, Room 3419, 400 7th Street SW., Washington, D.C. 20590.



driving in an efficient manner is obtained through the visual senses. The driver at night is presented with an extremely difficult task in a moving vehicle where the luminance level of the background scene and on the roadway itself often shifts very rapidly. The driver's light/dark adaptation must change quickly and continually as the light level is changed. The ability to detect and recognize objects falls off rapidly as the light level decreases to the level typical of night driving. Glare from oncoming vehicles and adjacent roadside developments present problems. Visual acuity, contrast sensitivity, distance judgment, speed of seeing, and color discrimination are all impaired by the relative darkness of the night driving environment. Therefore, anything done to enhance night visibility is likely to improve driver performance.

In addition to lighting, the primary techniques used to ameliorate the night visibility problem has been through the retroreflective treatment of signs, pavement markings, and delineators, and improved vehicular headlamp systems. Prior to 1980, there had been considerable research involving those techniques in simple, uniform backgrounds, aimed at improving legibility of signs and the detection distance at which objects are seen along the highway. For many roadway situations, particularly on low volume, rural roads, these studies showed vehicular headlamp illumination with limited pavement markings (i.e., center lines) and signing was sufficient to provide the driver with the needed guidance information. However, as the roadway environment becomes more complex, vehicular headlamps and deteriorating traffic control devices (TCDs) cannot provide the information needed for efficiently carrying out the driving task.

Laboratory studies suggest that only a modest level of illumination, far lower than daylight, is required to provide the necessary conditions for effective performance in almost any night driving environment. The difficulty of the driver's task and, therefore, the quality of visual information needed, is largely dependent upon the complexity of inputs presented to the visual senses. Visual complexity is determined by road geometry, maneuvering of other traffic, adjacent land uses, advertising signs, pedestrian activity, weather, traffic control devices, lighting, and maintenance of road features, and many other factors. Also important is the degree of driver impairment by such factors as alcohol and drugs, age, vision problems, and fatigue.

At the present time the FHWA's research plans which address these subjects are based on the recognition that the most pressing research need is to develop an understanding of how operational complexity of the driving environment affects the various techniques being used to provide visual guidance information to the driver and how these techniques interact. This research builds on past knowledge to determine what techniques and equipment should be used in which specific situations and how often and by what methods TCDs should be refurbished or replaced.

Even upon the completion of the above research, the FHWA recognizes that a significant gap will exist between the new information (research results) and the successful adoption of acceptable minimum maintained retroreflection standards for TCDs. Therefore, the FHWA has decided to open a public docket to receive information concerning the practicality of developing retroreflection standards for TCDs as well as research and measuring methods/devices which would be needed to determine and to objectively measure retroreflection standards.

The FHWA has formulated the following questions and invites responses concerning the retroreflective performance of traffic control devices during periods of reduced visibility:

1. Are standards needed for minimum maintained retroreflective performance requirements for traffic control devices (traffic signs, barricades, pavement markings, delineators, hazard markers, etc.) including those devices used in work zones? Are maximum initial and maintained retroreflective performance requirements needed for any specific colors or applications?

2. Should standards be based on retroreflectivity measurements or on minimum distances at which traffic control devices need to be visible and comprehensible to a motorist under a wide range of driving environments and conditions?

3. Have any highway agencies established retroreflective performance standards for their traffic control devices? If so, what are the basis of the performance standards? How long have they been in use and are they adequate? What problems have developed through their use? How cost-effective are they? Are these existing practices or procedures being used by highway agencies to determine when traffic control devices need to be replaced or refurbished?

4. In establishing minimum maintained retroreflective requirements for traffic control devices, are there special needs to be considered such as the "design driver", driver information processing, aging motorists, glare sensitivity, vehicle characteristics (i.e., head lights, windshields, eye height), complex visual backgrounds, high information load, and weather? Should a table be developed similar to Table II-1, "A Guide for Advance Warning Sign Placement Distance" as shown on page 2c-2a of the MUTCD?

5. Should there be retroreflection uniformity within a single sign or of signs within a single display or should certain signs have higher retroreflection than other signs for example, Stop signs as compared to Do Not Litter signs? Are there available data or research results for classifying (in order of sign of importance) traffic sign retroreflection needs?

6. Should traffic control devices retroreflective requirements be indicated in Specific Intensity per unit Area (SIA)<sup>3</sup>, Coefficient of Luminous Intensity (CIL) per unit area,<sup>4</sup> luminance<sup>5</sup>, or other units?

7. What instruments and procedures for measuring retroreflection of traffic control devices should be specified, are being used, or are available for use? If instruments or procedures have been used, were they practical and satisfactory?

8. What research studies are needed to develop reasonable performance standards?

9. What research studies are needed to develop performance measuring instruments?

10. Would comprehensive standards be cost-effective? Why or why not?

This advance notice of proposed rulemaking to the MUTCD is issued under the authority of 23 U.S.C. 109(d), 315, and 402(a), and the delegation of authority in 49 CFR 1.48(b).

It is anticipated that any proposed changes to the MUTCD resulting from the comments received would be included in a subsequent Notice of Proposed Rulemaking.

The FHWA had determined, at this time, that this document contains neither a major rule under Executive Order 12291 nor a significant proposal under the regulatory policies and procedures of the Department of Transportation. This determination will

<sup>3</sup> SIA: Candelas per footcandle per square foot.

<sup>4</sup> CIL per unit area: Candelas per lux per square metre (Metric equivalent of SIA).

<sup>5</sup> Luminance: Foot-lamberts (English), Candelas per square metre (Metric).



be reevaluated and a draft regulatory evaluation will be prepared, if necessary based upon the data received in response to this advance notice. Based upon the information available to the FHWA at this time, the action proposed in this advance notice will not have a significant economic impact on a substantial number of small entities.

#### List of Subjects in 23 CFR Parts 625 and 655

Design standards, Grant programs—transportation, Highways and Roads, Signs, Traffic regulations, Incorporation by reference.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: April 22, 1985.

R.A. Barnhart,

Federal Highway Administrator, Federal Highway Administration.

[FR Doc. 85-10178 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-22-M

#### DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

#### 24 CFR Part 207

[Docket No. R-85-1106; FR-1756]

Cooperative Housing Mortgage Insurance—Subordinated Secretary-Held Mortgages

#### Correction

In FR Doc. 85-9564 beginning on page 15754 in the issue of Monday, April 22, 1985, make the following correction: On page 15756, in the first column, the section heading "§ 207.2598" should read "§ 207.258".

BILLING CODE 1505-01-M

#### DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 936

Permanent State Regulatory Program of Oklahoma

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

#### ACTION: Proposed rule.

**SUMMARY:** OSM is proposing to modify the deadline for Oklahoma (1) to promulgate rules governing the training, examination and certification of blasters and (2) to develop and adopt a program to examine and certify all persons who are directly responsible for the use of explosives in a surface coal mining operation. On April 5, 1985, Oklahoma requested an extension of time for the development of a blaster certification program until August 5, 1985. All States with regulatory programs approved under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act) were required to develop and adopt a blaster certification program by March 4, 1984. Section 850.12(b) of OSM's regulations provides that the Director, OSM, may approve an extension of time for a State to develop and adopt a program upon a demonstration of good cause.

**DATE:** Comments not received by May 28, 1985 at the address below, no later than 5:00 p.m. will not necessarily be considered.

**ADDRESS:** Written comments should be mailed or hand delivered to Mr. Robert L. Markey, Director, Tulsa Field Office, Office of Surface Mining, Room 3014, 333 West 4th Street, Tulsa, Oklahoma 74103.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert L. Markey, Director, Tulsa Field Office, Office of Surface Mining, Room 3014, 333 West 4th Street, Tulsa, Oklahoma 74103; Telephone: (918) 581-7927.

**SUPPLEMENTARY INFORMATION:** On March 4, 1983, OSM issued final rules effective April 14, 1983, establishing the Federal standards for the training and certification of blasters at 30 CFR Chapter M (48 FR 9486). Section 850.12 of these regulations stipulates that the regulatory authority in each State with an approved program under SMCRA shall develop and adopt a program to examine and certify all persons who are directly responsible for the use of explosives in a surface coal mining operation within 12 months after approval of a State program or within 12 months after publication date of OSM's rule at 30 CFR Part 850, whichever is later. In the case of Oklahoma's program, the applicable date is 12 months after publication date of OSM's rule, or March 4, 1984.

On April 11, 1984, the State of Oklahoma submitted to OSM a draft proposed amendment its permanent regulatory program intended to implement the provisions of 30 CFR Part 850 relating to blaster training, examination and certification. As a

result of OSM's preliminary review, deficiencies were identified in Oklahoma's draft proposal. After reviewing OSM's concerns in light of available staff resources and existing workload commitments, it became apparent that additional time would be needed; therefore, the State on April 5, 1985, requested a four month extension of time, until August 5, 1985, to submit to OSM a comprehensive and complete proposed program amendment concerning the development and adoption of a blaster certification program in Oklahoma.

Therefore, OSM is seeking comment on the State's request for additional time to develop and adopt a blaster certification program. Section 850.12(b) of OSM's regulations provides that the Director, OSM, may approve an extension of time for a State to develop and adopt a program upon a demonstration of good cause.

#### Additional Determinations

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule would not impose any new requirements; rather, it would ensure that existing requirements established by SMCRA and the Federal rules would be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

#### List of Subjects in 30 CFR Part 936

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Authority: Pub. L. 95-87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*)



Dated: April 19, 1985.

Brent W. Blauch,

Acting Director, Office of Surface Mining.

[FR Doc. 85-10152 Filed 4-25-85; 8:45 am]

BILLING CODE 4310-05-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[OPTS-50523; FRL-2743-3]

#### 4,4'-Methylenebis(2-Chlorobenzeneamine); Proposed Determination of Significant New Use

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing a significant new use rule (SNUR) for the chemical substance 4,4'-methylenebis(2-chlorobenzeneamine) (MBOCA). The substance also is called 4,4'-methylenebis(2-chloroaniline). The Agency is proposing that the manufacture of MBOCA in the United States be designated as a significant new use of that chemical substance. Persons intending to engage in this significant new use would be required to submit a significant new use notice to EPA at least 90 days prior to the commencement of that use. The purpose of this SNUR is to ensure that EPA will receive notification of any proposed manufacture of MBOCA, allowing the Agency to regulate this activity before it occurs, if necessary.

**DATE:** Written comments on this proposed rule should be submitted by May 29, 1985.

**ADDRESS:** Comments should bear the docket control number OPTS-50523 and should be submitted to the following address: TSCA Public Information Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M. St., SW., Washington, D.C. 20460.

All written comments on this proposed rule will be available for public inspection in Rm. E-107 at the address given above from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M. St., SW., Washington, D.C. 20460. Toll free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:** OMB Control Number 2070-0038.

#### I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a significant new use. This determination is made by rule after consideration of all relevant factors, including those listed in section 5(a)(2). Once a use of a chemical substance is determined to be a significant new use, persons must, under TSCA section 5(a)(1)(B), submit a notice to EPA at least 90 days before they commence that significant new use.

Chemical substances subject to proposed or final SNURs are subject to the export reporting requirements to TSCA section 12(b). These requirements appear at 40 CFR Part 707. Chemical substances subject to final SNURs also must comply with TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of these requirements is codified at 40 CFR Part 707.

#### II. Applicability of General Provisions

In the Federal Register of September 5, 1984 (49 FR 35011), EPA promulgated general provisions applicable to SNURs (40 CFR Part 721, Subpart A). EPA is proposing that these general provisions apply to this SNUR, except as discussed in this preamble and as provided in the rule. The general provisions are discussed in detail in the cited Federal Register document, and interested persons should refer to that document for further information.

#### III. Summary of This Proposed Rule

The chemical substance identified in this proposed SNUR is 4,4'-methylenebis(2-chlorobenzeneamine) (GAS No. 101-14-4). The substance also is called 4,4'-methylenebis(2-chloroaniline). For purposes of convenience, the substance will be referred to as MBOCA in this proposed rule. The rule proposes that the manufacture of MBOCA in the United States be designated as a significant new use. The SNUR would apply to manufacturing processes of any type, regardless of the exposure controls used. Under this rule, persons intending to manufacture MBOCA in the United States would be required to notify EPA at least 90 days before they begin production.

Persons subject to this SNUR would be subject to the same notice requirements under TSCA section 5(a)(1) as submitters of premanufacture notices (PMNs). In particular, these requirements include the information

submission requirements of sections 5(b) and (d)(1), and the exemptions authorized by section 5(h). EPA has codified these notice requirements and the procedure for submitting notices in Subpart A of Part 721. Generally persons submitting a notice under this rule would be required to complete a PMN form with regard to their intended production of MBOCA. Note that potential manufacturers of MBOCA would be required to provide EPA with data on any processing and/or packaging of the substance that will occur at the manufacturing plant site.

Once EPA has received a SNUR notice, EPA may take regulatory action pursuant to sections 5(e), 5(f), 6, or 7 to control the substance. If no action is taken, section 5(g) requires the Agency to explain in the Federal Register its reasons for not taking action.

Although importation is included in the TSCA definition of "manufacture," importers of MBOCA would be exempted specifically from the requirements of this rule because the substance currently is being imported into the United States; this activity is an ongoing use and therefore cannot be identified as a significant new use. The SNUR also would not cover processing and use activities which occur away from the MBOCA manufacturing site, nor would it require information on the method of commercial distribution outside of the plant site. The Agency is considering a different regulatory approach to address potential health and environmental risks associated with these activities.

#### IV. Background Information on MBOCA

Based on information available to EPA, from 1 to 3.5 million pounds of MBOCA is used in the United States per year, mostly in the production of a variety of products having industrial and consumer uses. The primary use of MBOCA is as a hardener, or curing agent, in the manufacture of polyurethane elastomer products. The Agency believes that, at present, the entire amount of MBOCA used in the United States is imported; there is no current manufacture of the chemical substance in the United States, nor has there been since 1979.

EPA believes that MBOCA is a potential human carcinogen. Several chronic bioassays indicate that the substance causes malignant tumors in mice, rats, and dogs when administered orally. The bioassay in rats provided particularly strong evidence of carcinogenicity, involving a number of sites in the body. In addition, several structural analogues of MBOCA cause



malignant tumors in the urinary bladder of dogs (as does MBOCA) and are known inducers of malignant urinary bladder tumors in humans.

EPA has identified a number of different routes through which MBOCA can enter the human body: absorption through the skin, inhalation, and oral ingestion. Manufacture of the substance prior to 1979 is known to have resulted in the creation of MBOCA dust particles; human exposure to MBOCA in dust form would increase the likelihood that the substance will be absorbed into the body.

EPA has identified industrial workers (involved with MBOCA manufacture, processing, and/or distribution) as the population facing the greatest risk of exposure to the substance. The families of these workers may come in contact with MBOCA particles carried home on the clothing of the workers, although the degree of potential exposure is much less than for the workers themselves. Residents in communities surrounding plants that manufacture or process MBOCA also may be exposed to the substance—particularly children who play in dirt containing MBOCA particles. Because most of the substance is consumed during use in the polyurethane hardening process, the likelihood of consumer exposure is negligible.

Most of the background information discussed above was drawn from an Agency document entitled: Office of Toxic Substances Priority Review Level-1, Risk Assessment on MBOCA. This document is contained in the public record for this rulemaking.

#### V. Objectives and Rationale for the Proposed Rule

EPA is proposing this SNUR because the Agency wishes to achieve the following objectives with regard to the manufacture of MBOCA in the United States:

1. The Agency wants to ensure that it will receive notice of any company's intent to manufacture MBOCA before production begins.
2. The Agency wants to ensure that it will have an opportunity to review and evaluate data submitted in a SNUR notice (generally, the proposed method of manufacture and on-site processing and packaging) before manufacture of the substance begins.
3. The Agency wants to ensure that it will be able to regulate prospective manufacturers of MBOCA before risks from manufacture and related on-site activities occur, provided that the degree of potential health risk is sufficient to warrant such regulation.

There is no current exposure risk posed by MBOCA manufacture in the United States because the substance is not being produced in this country at this time. However, significant quantities of the substance are used in the United States as intermediates in the manufacture of polyurethane plastics, utilizing imported MBOCA. In view of the size of the market for MBOCA in the United States and the fact that there is no Federal restriction on manufacture of the substance at present, it is possible that one or more companies may commence manufacture of MBOCA in this country (provided they meet any state restrictions that may apply). EPA knows of a company that intends to begin producing the substance in the United States sometime in the near future (see Unit VI). EPA believes that the likelihood that the substance will be produced in the United States forms a basis for this rule.

Because MBOCA is a potential human carcinogen, the Agency wishes to ensure that all future manufacture of the substance in the United States will restrict the release of MBOCA dust. Previous manufacture of the substance at a plant site in Adrian, Michigan resulted in the release of a considerable amount of MBOCA dust particles, and resulting human exposure. EPA wishes to avoid a recurrence of this type of incident. The Agency believes that a SNUR which designates the manufacture of MBOCA in the United States as a significant new use of the substance is the best available regulatory means of achieving this objective.

This type of SNUR will ensure that EPA receives timely notification of any intent to manufacture MBOCA, thus enabling the Agency to conduct a complete assessment of the health and environmental risks associated with manufacturing and on-site processing of the substance. Moreover, the SNUR will provide mechanisms for immediate follow-up regulatory action through sections 5(e) and (f) of TSCA, thus enabling EPA to control (if necessary) the intended manufacture of MBOCA before unreasonable health or environmental risk occur.

EPA has considered the four factors listed in section 5(a)(2) (and others), as required by TSCA, and believes that the manufacture of MBOCA in the United States would be a significant new use of the substance. The Agency interprets the phrase "significant new use" as an exposure-related term, with the potential for release of a chemical substance and exposure to that substance determined by the factors listed in section 5(a)(2) and other factors

that EPA finds relevant on a case-by-case basis. A resumption of MBOCA manufacture in the United States would cause a significant increase in the potential for release of MBOCA and subsequent human exposure to the substance. Moreover, that use is not currently ongoing, nor has it occurred for over five years. Thus, the Agency believes that the commencement of the use designated in this proposed rule would present EPA with a significant new exposure concern that warrants the promulgation of a SNUR for that use.

#### VI. Applicability of Proposed Rule to Uses Occurring Before Promulgation of Final Rule

EPA finds that the intent of section 5(a)(1)(B) is best served by determining whether a use is a significant new use as of the proposal date of the SNUR rather than as of promulgation of the final rule. If uses began during the proposal period of the SNUR were not considered to be significant new uses, it would be very difficult for the Agency to establish SNUR notice requirements, because any person could defeat the SNUR by initiating a proposed significant new use before the rule became final. Based on this interpretation of TSCA section 5, EPA will determine whether the manufacture of MBOCA in the United States is a significant new use of the substance as of the date this rule is proposed.

EPA recognizes that this interpretation of the Act may disrupt the commercial activities of persons who begin manufacturing MBOCA in the United States after this rule is proposed but before promulgation of the final rule. These persons would be required to cease production and submit a SNUR notice as of the effective date of the final rule. However, this proposed rule provides any such persons with notice that the Agency intends to promulgate a SNUR for the manufacture of MBOCA, and any person commencing manufacture of MBOCA in the United States prior to promulgation of this SNUR would do so at their own risk.

This policy will have a direct impact on the company that already has indicated to EPA its intent to manufacture MBOCA. The company is developing a new process for manufacturing the substance. EPA intends that this company will be subject to the SNUR, because the Agency wishes to evaluate the company's manufacturing process and the potential exposure risks associated with that process. However, because EPA currently is aware of the company's intent to commence manufacture of



MBOCA, the Agency also does not want to cause the company unnecessary delay in beginning manufacture. (It should be emphasized that EPA will use its full TSCA authority to control the company's manufacturing and on-site processing of MBOCA should the Agency determine that such activity will present an unreasonable risk to human health or the environment.)

In view of the unique circumstances of this case, EPA has included language in the proposed rule which would allow any company to comply with the SNUR before the rule is promulgated. If a company were to meet all of the conditions of advance compliance, as specified in the regulatory language and described below, the company would be exempt from the requirements of the final SNUR. EPA is proposing this provision for public comment as part of this SNUR. However, the Agency also is considering the addition of an advance compliance exemption to the general provisions of 40 CFR 721, Subpart A (§ 721.19, Exemptions).

The first requirement for advance compliance with this SNUR would be to submit a complete significant new use notice to EPA. Any firm that submits an advance SNUR notice for MBOCA would be required to follow the general notification requirements of Subpart A, § 721.10. The company would have to submit the notice to the Agency at least 90 days before it begins manufacturing MBOCA. EPA would expect to complete its review of the notice within 90 days of receipt, but the Agency could extend its review period for up to 90 additional days, if necessary. The notice would have to contain all requisite SNUR data, with limitations described in this rule, including information on the company's intended method of manufacture and on-site processing of MBOCA.

EPA's procedures for the receipt, handling, and evaluation of advance significant new use notices under this rule would be the same as for any other significant new use notices. The Agency would publish a notice of receipt in the *Federal Register*, as required by section 5(d)(2) of TSCA. Non-confidential data from the advance notice would be added to EPA's public file for SNUR notices. The Agency then would conduct an evaluation of all data from the advance SNUR notice, together with any other relevant data in EPA's possession. The Agency would determine whether the planned manufacture and on-site processing of MBOCA would adequately control release of the substance (and thus not present an unreasonable risk to human health or

the environment), and whether further regulatory action would be required.

There are four possible situations which may occur after EPA completes its review of an advance significant new use notice.

1. If there is sufficient information for EPA to conclude that the company's intended method for manufacturing and on-site processing of MBOCA would present no unreasonable risk to human health or the environment under any reasonable risk to human health or the environment under any reasonably foreseeable circumstances, the Agency would take no further regulatory action with regard to the company. Under his option, EPA would notify the company that it could begin the significant new use after the Agency's review period ends. The company would be allowed to continue such use after the final SNUR becomes effective, without delay or the need to comply further with the rule.

2. If there is no sufficient information for EPA to reasonably determine whether the company's method for manufacturing and on-site processing of MBOCA would present an unreasonable risk under any reasonable foreseeable circumstances, but the Agency believes that the intended methodology would not pose such a risk if certain procedures or restrictions are followed (until additional data demonstrated them to be unnecessary), the Agency would attempt to negotiate a section 5(e) consent order with the company. The consent order would specify that the firm must use the approved methodology (as modified by EPA) in its manufacture and on-site processing of MBOCA. If a consent order is signed, it would go into effect on the effective date of the final rule. The company would not be able to deviate from the terms of the order after the effective date without being in violation of the Act.

Once a consent order is signed, the company would be allowed to begin the significant new use under the terms of the order, once the review period for the significant new use notice ends. The firm would not be allowed to deviate from the conditions of the consent order prior to the effective date of the order and the final SNUR; if the firm should deviate from those conditions, the company would not qualify for an advance compliance exemption. In such a case, the company would be required to cease manufacture of MBOCA on the effective date of the SNUR; the firm then would have to submit a significant new use notice and wait until completion of the statutory review period before resuming production. After submission of that notice, EPA would be able to

take action under section 5(e) in an adversarial context, if necessary.

3. If there is not sufficient information for EPA to reasonably determine whether the company's method for manufacturing and on-site processing of MBOCA would present an unreasonable risk under any reasonably foreseeable circumstances, and EPA and the company are not able to negotiate the terms of a consent order, the firm would not qualify for an advance compliance exemption under this SNUR. The company therefore would be subject to the requirements of the final SNUR as though it had not submitted an advance significant new use notice.

4. If there is sufficient information for EPA to reasonably conclude that the company's intended method for manufacturing and on-site processing of MBOCA would present an unreasonable risk to human health and the environment, and the Agency believes that the risk requires immediate control, EPA could take action under TSCA section 6(a) (made immediately effective under section 5(f)) or section 7 to control the risk. The Agency would not pursue a section 5(e) consent order in this case; the company therefore would not have met all of the conditions of the advance compliance exemption. The firm would be required to cease production (if not already done) on the effective date of the final SNUR, submit a significant new use notice, and wait until completion of the statutory review period before resuming production.

The Agency believes that its approach to advance SNUR compliance is an acceptable means of accomplishing its risk assessment and risk management objectives regarding possible significant new uses, without causing members of the regulated community to suffer unnecessary delays in their business activities. The advance compliance exemption in this rule would not waive EPA's enforcement authority with regard to any SNUR notice submitter. EPA solicits comment on this approach.

EPA is allowing the company that currently intends to manufacture MBOCA in the United States to seek an exemption from the final SNUR under the advance compliance provision that is being proposed in this rule. The Agency is doing so to enable the company to avoid a major delay in its manufacture of MBOCA, provided that the firm's intended method of manufacturing and on-site processing will not present an unreasonable risk to human health or the environment. EPA has allowed the company to submit an advance significant new use notice for MBOCA, and the Agency is handling the



notice as though the advance compliance exemption were in effect. EPA published a Notice of Receipt in the *Federal Register* of September 24, 1984 (49 FR 37460). The company now will have to meet all SNUR notice requirements, but will be able to avoid a delay in its intended manufacture of MBOCA if it meets all terms of the advance compliance exemption.

If that exemption is included in the final rule, the company will be able to benefit from it. However, if the advance compliance exemption is not included in the final rule, the company (and all other persons intending to manufacture MBOCA in the United States) will be required to comply with the final SNUR when it goes into effect.

#### VII. Test Data

EPA recognizes that under TSCA section 5 a person is not required to develop any particular test data before submitting a significant new use notice. Rather, a person is only required to submit test data in that person's possession or control and to describe any other data known to or reasonably ascertainable by that person.

However, in view of the potential health and environmental risks that may be posed by the manufacture of MBOCA, EPA encourages SNUR notice submitters to provide the Agency with any relevant test data on MBOCA that they may wish to develop. Generally, SNUR notices (for MBOCA or any other chemical substance) submitted with relevant test data would improve EPA's ability to conduct a reasoned evaluation of the health and environmental effects of the subject chemical substance. Persons choosing to develop test data voluntarily in response to the SNUR should provide data that conform with the standards of TSCA good laboratory practices, which are codified at 40 CFR Part 792 and were published in the *Federal Register* of November 29, 1983 (48 FR 53923). EPA encourages persons who intend to conduct testing of MBOCA to consult with the Agency before selecting a protocol for testing the substance.

Finally, EPA urges persons submitting SNUR notices on MBOCA to provide information on the potential benefits of MBOCA, plus information on the risks posed by the substance compared to risks posed by potential substitutes. Again, the more information EPA receives on MBOCA, the better the Agency's evaluation of health and environmental risks will be.

#### VIII. Economic Impact

EPA estimates that the cost of submitting an individual SNUR notice in

response to this rule would be between \$1,400 and \$8,000. The SNUR notice submitter also may incur the costs of some voluntarily adopted exposure control measures that would not have been utilized but for the existence of the SNUR; it is not possible to quantify these costs without knowing what control measures are adopted, because exposure control methodologies vary within the chemical industry. In addition, the notice submitter may incur up to a 3.2 percent reduction in profits due to delays in manufacture resulting from the Agency's notice review period, plus the cost of compliance with any regulatory follow-up action that may be taken by EPA.

In the case of a company that submits a SNUR notice to EPA prior to promulgation of the final rule, the firm will be less likely to experience delays in manufacture or reduction in profits if it complies with all of the requirements of the advance compliance exemption in the rule.

EPA is not able to determine the total cost of this rule for the industry as a whole, because it is not possible to estimate accurately the number of companies that will submit SNUR notices in response to this rule; at present, the company that is seeking to comply with this SNUR prior to promulgation of the rule is the only respondent known or anticipated by EPA.

The Agency believes that this rule may have a slight impact on innovation within the chemical industry, because certain companies that intend to manufacture MBOCA in the United States may abandon their plans to do so as a result of this SNUR (without submitting a SNUR notice). Although these firms will not incur the direct cost of SNUR compliance, they (and society) may lose some of the benefits that would have been derived from the manufacture of MBOCA. However, the rule also may encourage innovation by companies that seek new methods to control MBOCA release and exposure.

This SNUR will provide health and environmental benefits to society by enabling the Agency to monitor and, if necessary, control exposure to MBOCA resulting from manufacture of the substance in the United States. As with total industry cost, it is not possible to quantify these benefits with any degree of accuracy, because it is not possible to determine the number of companies that will submit SNUR notices.

For a more detailed discussion of economic impact, see the Economic Analysis of the Proposed SNUR for MBOCA. This document is contained in

the public record for this rule (OPTS-50523).

#### IX. Judicial Review

When the final version of this rule is promulgated, judicial review may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or in the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA intends to promulgate this rule for purposes of judicial review two weeks after publishing the final rule in the *Federal Register*. The effective date will be calculated from the promulgation date.

#### X. Rulemaking Record

EPA has established an administrative record for this rulemaking (docket control number OPTS-50523). The record includes basic information considered by the Agency in developing this proposed rule. EPA will supplement the record with additional relevant information as it is received. The record now includes the following:

1. Office of Toxic Substances Priority Review Level-1 Document, Risk Assessment on MBOCA, U.S.E.P.A., 1982.

2. Economic Analysis of Proposed Significant New Use Rule for 4,4'-methylenebis(2-chlorobenzeneamine) (MBOCA), Economics and Technology Division, U.S.E.P.A., 1984.

3. Other relevant factual information and support documents.

The Agency will accept additional materials for inclusion in the record at any time between the date of publication of this proposed rule and the designation of the complete record. EPA will identify the complete rulemaking record by the date of promulgation of the final rule.

The record is available to the public in the OTS Public Information Office, from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. The Public Information Office is located in Rm. E-107, 401 M St., SW., Washington, D.C.

#### XI. Regulatory Assessment Requirements

##### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this SNUR would not be a "major" rule because it will not have an impact on the economy of \$100



million or more, and it will not have a significant effect on competition, costs, or prices. EPA estimates that the reporting cost for submitting a notice under this rule will be approximately \$1,400 to \$8,000. At this time, the Agency knows of only one potential manufacturer of MBOCA. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact will be limited because such factors are unlikely to discourage an innovation that has high potential value. Moreover, the rule may encourage SNUR respondents to develop new methods for controlling release and exposure to MBOCA.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

#### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), EPA certifies that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small businesses. The Agency has not determined whether parties affected by this rule are likely to be small businesses. However, EPA believes that few manufacturers would submit SNUR notices under this rule. Therefore, although the costs of preparing a SNUR notice might be significant for some small manufacturers, the number of such firms affected is not expected to be substantial.

#### C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule, under the provisions of

the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has assigned control number 2070-0038 to the rule. Comments on these information requirements should be submitted to the OMB Office of Information and Regulatory Affairs and marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

(Sec. 5, Pub. L. 94-409, 90 Stat. 2012 (15 U.S.C. 2604))

#### List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: April 17, 1985.

Lee M. Thomas,  
Administrator.

#### PART 721—[AMENDED]

Therefore, it is proposed that Part 721 of Chapter I of Title 40 be amended by adding § 721.275 to read as follows:

##### § 721.275 4,4'-methylenebis(2-chlorobenzeneamine) (MBOCA).

(a) *Chemical substance and significant new use subject to reporting.*

(1) The chemical substance 4,4'-methylenebis(2-chlorobenzeneamine) (CAS No. 101-14-4) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The substance also is identified as 4,4'-methylenebis(2-chloroaniline) and MBOCA.

(2) The significant new use is the manufacture of the substance in the United States.

(b) *Specific requirements.* The provisions of Subpart A of this Part apply to this section except as modified by this paragraph.

(1) *Exemptions.* The following persons are exempt from the reporting requirements of this section:

(i) A person who imports MBOCA into the customs territory of the United States and does not otherwise manufacture the substance in the United States.

(ii) A person who complies with the requirements of this section and Subpart A of this Part prior to the effective date of this section and receives written notification of compliance from EPA at the end of the notice review period specified in § 721.10. EPA will so notify the person only if one of the following occurs:

(A) EPA determines that there is no need for immediate regulatory action concerning the activities described in the significant new use notice.

(B) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to go into effect on the effective date of this section, and the person complies with the terms of any such consent order before the order goes into effect.

(2) *Notice requirements and procedures.* A person who is required to submit a significant new use notice under this section must complete only Parts I.A., I.B., I.C.1., I.C.3., II.A., and III. of the notice form specified in § 721.10. The person is not required to submit information about processing or use by other persons of the substance identified in paragraph (a)(1) of this section.

[FR Doc. 85-10289 Filed 4-25-85; 8:45 am]

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# Notices

Federal Register

Vol. 50, No. 81

Friday, April 23, 1985

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## ADVISORY COUNCIL ON HISTORIC PRESERVATION

### Programmatic Memorandum of Agreement on the Activities of the Department of the Army at Fort Leavenworth, KS

**AGENCY:** Advisory Council on Historic Preservation.

**ACTION:** Notice.

**SUMMARY:** This notice provides information about and invites comments on a proposed Programmatic Memorandum of Agreement that provides for the development of a Preservation Plan for the identification, inventory, evaluation and treatment of historic, architectural and cultural properties at Fort Leavenworth, Kansas.

Comments Due: Comments must be submitted on or before May 28, 1985.

**ADDRESS:** Executive Director, Advisory Council on Historic Preservation, The Old Post Office, 1100 Pennsylvania Avenue, NW., Room 809, Washington, DC 20004.

The Council proposes to execute a Programmatic Memorandum of Agreement pursuant to § 800.8 of its regulations (36 CFR Part 800) with the Department of the Army and the Kansas State Historic Preservation Officer. The proposed Agreement establishes standards for a Preservation Plan at Fort Leavenworth which will coordinate the management of historic, architectural and cultural properties with the activities of the Army on the Fort. The Army's responsibilities at the Fort pursuant to sections 106 and 110(f) of the National Historic Preservation Act will be fulfilled by implementation of the proposed Agreement. Interested parties are encouraged to obtain a copy of the proposed Agreement from the Council and submit comments.

Dated: April 23, 1985.

Robert R. Garvey,  
Executive Director.

[FR Doc. 85-10167 Filed 4-25-85; 8:45 am]

BILLING CODE 4310-10-M

## DEPARTMENT OF AGRICULTURE

### Competitive Research Grants Program for Forest and Rangeland Renewable Resources for Fiscal Year 1985; Solicitation of Applications

#### Competitive Research Grants Program for Forest and Rangeland Renewable Resources

Notice is hereby given that pursuant to the authority contained in Section 5 of the Forest and Rangeland Renewable Resources Research Act of 1978, as amended (16 U.S.C. 1644), Competitive Research Grants (CRG) of the Office of Grants and Program Systems (OGPS), United States Department of Agriculture (USDA), anticipates awarding standard project grants for basic research in the areas of harvesting, wood utilization and forest biology. The total amount expected to be available for this program during Fiscal Year 1985 is approximately \$7,500,000. Long-term projects, up to a limitation of five years, are encouraged. Grants will be awarded by CRG to the extent that funds are available.

Pursuant to the Secretary's Memorandum number 1030-12 dated April 12, 1985, the authority to administer the \$7,840,000 made available by section 101(c) of the Continuing Appropriations Act for Fiscal Year 1985 for a competitive research grants program for forest research authorized by Section 5 of the Forest and Rangeland Renewable Resources Research Act of 1978 has been transferred along with the funding to the Office of Grants and Program Systems. Under this authority the Office of Grants and Program Systems may award grants to Federal, State, and other governmental agencies, public or private agencies, institutions, universities, and organizations, and businesses and individuals in the United States. Proposals received from scientists at non-United States organizations or institutions will not be considered for support.

For purposes of this program in Fiscal Year 1985, CRG is adopting the

Administrative Provisions governing the Competitive Research Grants Program, 7 CFR Part 3200 (excluding Sections 3200.1, 3200.3(a), 3200.4(c), modifying the second sentence of 3200.6(c)(3) by deleting the words "food and agricultural sciences" and inserting in lieu thereof "protection, management and utilization of forest and rangeland renewable resources," and deleting the parenthetical phrase in the last sentence of 3200.7(c)), found at 49 FR 5570, February 13, 1984, as amended by 50 FR 5499, February 8, 1985. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and awarding of grants, and regulations relating to the post-award administration of grant projects. Copies of these provisions and of the Research Grant Application Kit may be obtained by writing to the address listed below or by calling (202) 475-5049. For reasons set forth in the Final rule related notice related to 7 CFR Part 3015, Subpart V (48 F.R. 29115, June 24, 1983), this program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

An original and 15 copies of each proposal submitted under this program are requested. This number of copies is necessary to permit thorough, objective peer evaluation of all proposals received before funding decisions are made. In addition to other required forms and certifications included in the Research Grant Application Kit, it is requested that an original and 15 copies of Form S&E-661, "Grant Application," also be submitted. Proposers should note that one copy of this form must contain pen-and-ink signatures of the principal investigator(s) and the authorized organizational representative.

All copies of each proposal should be mailed in one package if at all possible. Due to the volume of proposals received, applications submitted in several packages are very difficult to identify. If copies of a proposal must be mailed in more than one package, however, the number of pages should be clearly marked on the outside of each. It is important that all packages be mailed at the same time. Also, please see that each copy of each proposal is stapled securely in the upper left-hand corner. DO NOT BIND. Information should be typed on one side of the page only.



Every effort should be made to ensure that the proposal contains all pertinent information when submitted. Prior to mailing, compare your proposal with the Application Requirements checklist contained in the Research Grant Application Kit and instructions found in 7 CFR Part 3200.

Each research grant application must be submitted by the time limit set below to: Proposal Services Unit, Grants Administrative Management, Office of Grants and Program Systems, U.S. Department of Agriculture, Room 010, Justin Smith Morrill Building, 15th and Independence Avenue, SW., Washington, D.C. 20251.

To be considered for funding during Fiscal Year 1985, proposals must be received in Grants Administrative Management by the close of business on June 7, 1985.

One copy of each proposal not selected for funding will be retained for a period of one year. The remaining copies will be destroyed.

#### Introduction to Program Description

Standard research grants will be awarded to support basic research in selected areas of (1) harvesting, processing, and utilization of timber resources, with special emphasis on the chemical, mechanical, and engineering properties of wood and wood materials and (2) forest biology, including biotechnology, that are considered by a number of scientific groups to possess exceptional opportunity for fundamental scientific discovery and for contributing in the long run, to applied research and development vitally needed on important wood utilization and forestry problems. This grants program recognizes that new, innovative approaches and enhanced levels of funding are essential as we seek ways to improve the economic and environmental value of our forest resources.

Consideration will be given to research proposals that address fundamental questions in the areas noted below and that are consistent with the long-range missions of USDA. Basic guidelines are provided to assist members of the scientific community in assessing their interest in the program areas and to delineate certain important areas where new information is vitally needed. However, these guidelines are also meant to be flexible and should not detract from the creativity of potential investigators. The Competitive Research Grants office encourages the submission of innovative projects in the so-called "high-risk" category, as well as those that may have greater probability of success.

Workshops or symposia that bring together scientists to identify research needs, update information, or advance an area of research are recognized as an integral part of research efforts. Support for a limited number of such meetings covering subject matter encompassed by this Competitive Research Grants Program for Forest and Rangeland Renewable Resources will be considered for partial or, if modest, complete support.

This program is divided into the two program areas outlined below, and funding will be divided equally between them. Proposals submitted in response to this solicitation must be identified as to the program area under which they are to be considered for funding (e.g., 1.1).

First, the Department will fund proposals concerning the improved utilization of wood and wood fiber. Public and private forests in the United States contain one of our most important renewable natural resources, providing a continuing supply of wood for industrial materials, chemicals, and energy, as well as other resources and benefits. National requirements for wood, wood fiber, and chemical products, however, increasingly demand the development of innovative and economical conversion processes that effectively utilize total available wood resources. Thus, as the diverse demands placed upon forest resources grow, the Department of Agriculture is encouraging the development of more efficient harvesting, utilization, and management practices.

Second, the Department will fund proposals concerning forest biology (including biotechnology). Forest systems generally are dominated by long-lived trees in either planted or naturally regenerated stands that may vary in composition from one species to complex mixtures of many. These primarily undomesticated populations of forest trees, while dominant, are but one component of larger communities of diverse numbers and combinations of associated organisms. Productivity of the forest ecosystem is thus dependent upon the many complex processes and interactions among trees, other organisms and the physical factors of the environment. While many of these processes and interactions have been identified, studied and described, very little is known of the basic biological mechanisms that underlie and determine their directions and rates.

The following guidelines are provided as a base from which proposals may be developed.

#### Specific Areas of Research To Be Supported in Fiscal Year 1985

##### 1.0 Improved Utilization of Wood and Wood Fiber

Improved wood utilization practices depend upon a continually advancing scientific foundation of basic research in wood properties and fundamental components of wood science. This program area encourages research that addresses critical barriers to improved wood utilization, and that will provide the scientific base from which new research and development can proceed. Grants will be awarded to support basic research in the following three categories of wood science:

1.1 *Wood Chemistry and Biochemistry* represents an important area where new basic information is vitally needed and where breakthroughs have a virtually unlimited potential for expanding wood utilization. Basic questions that need to be addressed include the nature of underlying principles governing enzymatic, microbial, and other chemical reactions. Examples of research subjects of interest include bioconversion and deterioration mechanisms, lignin and cellulose polymer modification, surface chemistry, bonding chemistry, and thermal reactions.

1.2 *Physical/Mechanical Properties of Wood and Basic Processing Technology* constitutes an area of investigation in which an improved base of scientific knowledge can ensure future development of new products and processes. Research is encouraged that furthers our understanding of basic mechanisms that impinge upon the structure, physical properties, and basic processing characteristics of wood and reconstituted wood materials. Examples of such research include, but are not limited to, anatomical, viscoelasticity and quality investigations, cutting processes, heat and mass transfer phenomena, lignocellulose modification, particle/fiber consolidation, non-destructive property evaluation, and materials science principles.

1.3 *Structural Wood Engineering* has developed empirically over time and has typically involved incremental improvements upon conventional concepts. Significant improvements depend upon developing an expanded scientific base of knowledge about the use and performance of wood as a structural material. The goal of basic research in this field is to support and encourage innovative approaches to the structural use of wood. Examples of research in this category include reliability-based design, systems



modeling and validation, wood/non-wood composites, fasteners, and basic failure mechanisms.

To be considered for support, grant proposals should demonstrate applicability to one of the described areas of research emphasis and must offer a reasonable probability of contributing significantly to the present body of scientific knowledge. The Department encourages proposals that emphasize innovative approaches to solving fundamental problems in the field of wood science and technology. Although this program area will emphasize research in the above categories, other new or unusual approaches will not be excluded.

If necessary, further information may be obtained from the Associate Program Manager at (202) 475-5022.

## 2.0 Forest Biology (Including Biotechnology)

The primary goals of the Forest Biology program area are to promote and fund research that will further the basic knowledge of mechanisms of biological processes in forest organisms and systems, and that will contribute to overcoming barriers to optimize the health and productivity of the forest resource. Emphasis will be placed on research proposals that deal with the woody plant component of the forest system. Also, grants will be awarded to support basic studies in the following two categories of forest biology research, each of which has been judged to offer exceptional opportunities for scientific advancement. Thus, proposals in this area of fundamental research are encouraged, but the program will not exclude other new or unusual research approaches.

**2.1 Genetic Structure and Function** is an area of research in which new basic knowledge and technology development are critically needed to support future efforts in more intensive forest management. Forest organisms, by virtue of their wide distribution and occurrence in both natural and manipulated ecosystems, offer unique opportunities to analyze, identify and utilize a broad spectrum of variations and adaptations that still persist in the gene pools of existing populations.

Research should address the genetic limits to the health and productivity of woody species, including: Development of techniques for genetic engineering, including those for DNA transfer systems and for determining molecular mechanisms of gene expression; elucidation of mechanisms of morphogenesis at the cellular and organismal levels, including those controlling the development of

productive plants from tissue or cell culture; identification and characterization of valuable genes and simply-inherited traits; and determinations of the organization, structure, and function of genomes.

**2.2 Mechanisms of Interactions in Forest Systems** is an area of research which requires a significant increase in basic knowledge to support subsequent studies of a more applied nature. Forest productivity is determined by complex climatic, geochemical and physical forces interacting with the living component of the ecosystem, the diverse mixtures of woody species of varying genotype, size and age that exist in various stages of equilibria with each other and with a host of other forest organisms. Understanding basic mechanisms that underlie the dynamic changes that occur as a forest regenerates and matures is essential to determining constraints and opportunities to improve the health and productivity of the forest resource.

Areas in which basic research is needed to understand mechanisms involved in some of those processes include, but are not limited to: Determining the mechanisms driving the co-evolved synergistic processes of forest organisms such as mycorrhizal symbioses and nitrogen fixation; elucidating mechanisms involved in antagonistic relationships between forest organisms (interspecific interference) such as allelopathy and host-parasite interactions.

To be considered for support, grant proposals should demonstrate applicability to one of the described areas of research emphasis and must offer a reasonable probability of contributing significantly to the present body of scientific knowledge. It is especially important that proposals emphasize innovative approaches to solving fundamental problems in forest biology.

If necessary, further information may be obtained from the Associate Program Manager at (202) 447-7417.

## Supplementary Information

It has been determined that, because of the need to implement this program so that the research can be initiated in the late spring or early summer of 1986, compliance with the notice and public procedure provisions of 5 U.S.C. 553, made applicable to this solicitation by Departmental Policy, 36 FR 13804 as (1971), is impracticable and contrary to the public interest. Further, this action has been reviewed under Executive Order 12291 and it has been determined that it is not a major rule. Although this Notice establishes the procedures and

criteria under which the recipients of these grants in Fiscal Year 1985 will be selected, and the terms and conditions under which such grants will be administered, it does not involve a substantial or major impact on the Nation's economy or on large numbers of individuals or businesses.

There will be no major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504 (h)), the collection of information requirements contained in this rule have been approved under OMB Document No. 0525-0001. In addition, this regulation will not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354 (5 U.S.C. 601). No regulatory analysis is required.

Done at Washington, D.C., this 23rd day of April 1985.

Edgar L. Kendrick,

Administrator, Office of Grants and Program Systems.

[FR Doc. 85-10175 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-MT-M

## Commodity Credit Corporation

### Uniform Grain Storage Agreement; Uniform Rice Storage Agreement Annual Contract Fees

**AGENCY:** Commodity Credit Corporation, USDA.

**ACTION:** Notice of proposed determination of 1985-86 contract fees.

**SUMMARY:** The purpose of this notice is to propose changes in the amount of the contract fees which are collected from warehousemen by the Commodity Credit Corporation (CCC) in accordance with the regulations governing the Standards for Approval of Warehouses for Grain, Rice, Dry Edible Beans, and Seed, (7 CFR 1421.5551 *et seq.*). The fees are charged by CCC to defray the costs which are incurred in the periodic examination of warehouses operated by warehousemen who have storage agreements with CCC and do not have a Federal warehouse license or State warehouse license issued by a State having a cooperative agreement with CCC for warehouse examination services.

**DATE:** Comments must be received on or before May 28, 1985—in order to be assured of consideration.



**ADDRESS:** Send comments to Paul W. King, Director, Warehouse Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture, P.O. Box 2415, Washington, D.C. 20013, (202) 447-4018.

**FOR FURTHER INFORMATION CONTACT:** Steven Closson, Chief, Storage contract Branch, Warehouse Division, ASCS, USDA, Room 5962—South Building, P.O. Box 2415, Washington, D.C. 20013, (202) 382-8053.

**SUPPLEMENTARY INFORMATION:** This notice has been reviewed in conformity with Executive Order 12291 and Departmental Regulation 1512-1 and has been classified as "not major." This action has been classified "not major" since implementation of these proposed determinations will not result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local governments, or geographical region; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, the environment or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 28115 (June 24, 1983).

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since CCC is not required by 5 U.S.C. 553 or any provisions of law to publish a notice of proposed rulemaking with respect to the subject matter of this notice.

The Commodity Credit Corporation Charter Act (15 U.S.C. 714) provides authority for CCC to conduct a number of operations to stabilize, support, and protect farm income and prices. CCC is authorized to carry out such activities as making price support available with respect to various agricultural commodities, removing and disposing of surplus agricultural commodities, exporting or aiding in the exportation of agricultural commodities, and procuring agricultural commodities for sale both in the domestic market and abroad.

Section 4(h) of the CCC Charter Act provides that the Corporation shall not acquire real property in order to provide storage facilities for agricultural commodities unless CCC determines that private facilities for the storage of such commodities are inadequate. Further, Section 5 of the CCC Charter

Act provides that in carrying out the Corporation's purchasing and selling operations, and in warehousing, transporting, or handling of agricultural commodities, CCC is directed to use, to the maximum extent practicable, the usual and customary channels, facilities, and arrangements of trade and commerce.

Section 10 of the United States Warehouse Act, as amended (7 U.S.C. 251) provides that the Secretary of Agriculture shall charge, assess, and cause to be collected user fees with respect to all warehouses licensed under the United States Warehouse Act (USWA). The user fees are paid by federally licensed warehousemen to the Agricultural Stabilization and Conservation Service (ASCS) to defray the costs which are incurred with respect to (1) warehouse examinations under the USWA; (2) licenses issued to classify, inspect, grade, sample, or weigh agricultural commodities stored or to be stored under the USWA; and (3) warehouse licenses issued, amended, modified, extended, or reinstated under the USWA. CCC contracts with federally licensed warehouses and others in the conduct of its business and requires the periodic examination of all federally licensed warehouses which are the subject of a storage agreement with CCC. Because similar warehouse examination services are required for other warehousemen having a storage agreement with CCC, it was determined that CCC should collect an annual contract fee to offset the costs resulting from the periodic examination of those warehouses. CCC now collects an annual contract fee from warehousemen having a storage contract with CCC who do not have a Federal warehouse license or who do not have a State warehouse license issued by a State having a cooperative agreement with CCC for warehouse examination services.

The present contract fee schedule is found at 7 CFR 1427.5558. However, CCC has issued proposed regulations (FR) which would delete that fee schedule from the Code of Federal Regulations and provide that the amount of contract fees would be determined and announced annually in a publication in the Federal Register.

When contract fees were first established in 1981, CCC did not perform warehouse examinations directly but in accordance with a cooperation agreement under which CCC reimbursed the Agricultural Marketing Service (AMS) for performing this service. The warehouse licensing and examination responsibilities of AMS have since been transferred to the

ASCS, one of the agencies within the Department of Agriculture which provides support services for CCC.

A study of the present annual contract fees and warehouse license user fee assessments indicated that some adjustments are necessary to address two areas of concern. First, several large mergers of warehouse locations under a single CCC warehouse code or USWA license have occurred resulting in the assessment of the currently applicable maximum contract fee which is \$1,250. This has resulted in a disproportionate share of program costs incurred for warehouse examinations being collected from single location users. Because examination resources spent conducting multi-location examinations, including the examinations of multiple location warehouses which may have been merged under a single CCC warehouse code or USWA license, exceed resources spent examining a single location of the same capacity, it was felt the method of assessment should be changed to more equitably assess all users. Second, the placement of warehouse licensing, storage contract and examination warehouse functions within one agency (i.e., ASCS) are expected to lower overall program costs. The continued assessment of fees at present levels is unnecessary and these reduced costs should be passed along to all users of these services through a reduction of total fees assessed. Accordingly, it is proposed that the following schedule of fees and the method of determining such fees would be applicable to the 1985-86 contract year.

#### Proposed Determinations

Comments are requested on the following proposed determinations with respect to contract fee schedule and method of fee determination to be used during the 1985-86 contract year. The fees set forth in the proposed schedule will be collected by the Commodity Credit Corporation (CCC) from warehousemen who have a storage contract with CCC but who do not have a Federal warehouse license or a State warehouse license issued by a State having a cooperative agreement with CCC for warehouse examination services.

#### FEE SCHEDULE

Location grain capacity (bushels)	Annual contract fees (dollars)
1 to 150,000	\$100
150,001 to 250,000	200
250,001 to 500,000	300
500,001 to 750,000	400



## FEE SCHEDULE—Continued

Location grain capacity (bushels)	Annual contract fees (dollars)
750,001 to 1,000,000	500
1,000,001 to 1,200,000	600
1,200,001 to 1,500,000	700
1,500,001 to 2,000,000	800
2,000,001 to 2,500,000	900
2,500,001 to 5,000,000	1,000
5,000,001 to 7,500,000	1,100
7,500,001 to 10,000,000	1,200
10,000,001 +	1,200

<sup>1</sup> Plus \$30 per million bushels of capacity above 10 million or fraction thereof.

The location capacity shall be determined by the Secretary of Agriculture and shall be the capacity of a fully functional facility operated as a public warehouse or functional unit of a group of warehouses usually within the same town or freight tariff point. A functional facility is one which could operate independently if it was separated from other facilities in the merger. Any outlying unit which is not a fully functional facility would have its capacity included as part of the combined capacity of the nearest fully functional operating location.

The annual contract fee shall be the sum total of the fees for all functional units within the warehouse code and shall be assessed as required in the applicable storage agreement.

Signed at Washington, D.C., on April 23, 1985.

Everett Rank,

*Executive Vice President, Commodity Credit Corporation.*

[FR Doc. 85-10176 Filed 4-25-85; 8:45 am]

BILLING CODE 3410-05-M

## COMMISSION ON CIVIL RIGHTS

## Georgia Advisory Committee; Amendment

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Georgia Advisory Committee to the Commission originally scheduled for May 17, 1985, at Atlanta, Georgia, has a new convening date.

The meeting address and time will remain the same. The meeting date will change to May 10, 1985.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10121 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M

## Hawaii Advisory Committee; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Hawaii Advisory Committee to the Commission will convene at 4:00 p.m. and will end at 8:00 p.m., on May 16, 1985, at the Ala Moana Americana Hotel, 410 Atkinson Drive, the Board Room, Honolulu, Hawaii. The purpose of the meeting is to review information submitted by the public at its last meeting and conduct program planning for the remainder of fiscal year 1985.

Persons desiring additional information, or planning a presentation to the Committee, should contact Philip Montez, the director of the Western Regional Office at (213) 688-3437.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 22, 1985.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10118 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M

## Idaho Advisory Committee; Agenda for Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Idaho Advisory Committee to the Commission will convene at 9:00 a.m. and will end at 5:00 p.m., on May 16, 1985, at the Lewiston Community Center, 1424 Main Street, Lewiston, Idaho. The purpose of the meeting is to hold a community forum on Indian education—high drop out rate among Indian students in grades K-12.

Persons desiring additional information, or planning a presentation to the Committee, should contact Susan McDuffie, the director of the Northwestern Regional Office at (206) 442-1246.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 22, 1985.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10124 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M

## Maryland Advisory Committee; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Maryland Advisory Committee to the Commission will convene at 3:30 p.m. and will end at 4:30 p.m. on May 16, 1985, at the Baltimore Convention Center, 1 West Pratt Street, Room 302, Baltimore, Maryland. The purpose of the meeting is for an orientation of new members and discussion of program plans.

Persons desiring additional information, or planning a presentation to the Committee, should contact Edward Rutledge, director of the Mid-Atlantic Regional Office, at (202) 254-6717.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, DC, April 22, 1985.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10119 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M

## Ohio Advisory Committee; Meeting Cancellation

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Advisory Committee to the Commission originally scheduled for April 27, 1985, at the Clarion Hotel, 141 W. 6th Street, Cincinnati, Ohio, [FR Doc. 85-9039, on page 14741 has been cancelled.

Dated at Washington, D.C., April 19, 1985.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10122 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M

## Texas Advisory Committee; Amendment

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Texas Advisory Committee to the Commission originally scheduled for May 10, 1985, at Arlington, Texas, has a new convening time.

The meeting address and date will remain the same. The meeting time will change to 9:00 a.m. to 5:00 p.m.

Bert Silver,

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-10123 Filed 4-25-85; 8:45 am]

BILLING CODE 6335-01-M



**Virginia Advisory Committee; Agenda and Notice of Public Meeting**

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Virginia Advisory Committee to the Commission will convene at 1:30 p.m. and will end at 4:00 p.m. on May 17, 1985, at the School Board Annex Building, 102 North Street, NW., Leesburg, Virginia. The purpose of the meeting is to provide an orientation for new members and to discuss civil rights problems and issues in Virginia.

Persons desiring additional information, or planning a presentation to the Committee, should contact Edward Rutledge, director of the Mid-Atlantic Regional Office, at (202) 254-6717.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 22, 1985.

Bert Silver,  
Assistant Staff Director for Regional Programs.

[FR Doc. 85-10120 Filed 4-25-85; 8:45 am]

BILLING CODE 5335-01-M

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A-122-004]

**Steel Reinforcing Bars From Canada; Preliminary Results of Administrative Review of Antidumping Finding and Tentative Determination To Revoke in Part**

**AGENCY:** International Trade Administration/Import Administration, Commerce.

**ACTION:** Notice of preliminary results of administrative review of antidumping finding and tentative determination to revoke in part.

**SUMMARY:** The Department of Commerce had conducted an administrative review of the antidumping finding on steel reinforcing bars from Canada. The review covers the only manufacturer covered by this finding, Western Canada Steel Limited, and the two other known exporters to the United States of this merchandise manufactured by Western Canada Steel Limited. The review period is April 1, 1983 through March 31, 1984. There were no known shipments of this merchandise to the United States during the period and there are no known unliquidated entries.

As a result of the review, the Department has preliminary determined

to require cash deposits of estimated antidumping duties on future entries equal to the margin calculated on the last known shipments. The Department has tentatively determined to revoke the finding with respect to Western Canada Steel Limited.

Interested parties are invited to comment on these preliminary results and tentative determination to revoke in part.

**EFFECTIVE DATE:** April 26, 1985.

**FOR FURTHER INFORMATION CONTACT:** Sheila Forbes or John Kugelman, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC. 20230, telephone: (202) 377-2923/3601.

**SUPPLEMENTARY INFORMATION:****Background**

On May 8, 1984, the Department of Commerce ("the Department") published in the *Federal Register* (49 FR 19560) the final results of its last administrative review of the antidumping finding on steel reinforcing bars from Canada (29 FR 5341, April 21, 1964) and announced its intent to conduct the next administrative review. The Department has now conducted that administrative review.

**Scope of Review**

Imports covered by the review are shipments of steel reinforcing bars from Canada, manufactured by Western Canada Steel Limited, currently classifiable under items 806.7900 and 806.8100 of the Tariff Schedules of the United States Annotated.

The review covers Western Canada Steel Limited and the two other known exporters to the United States, Rhovaco Holdings Limited and Russelsteel Limited, to the United States of Canadian steel reinforcing bars manufactured by Western Canada Steel Limited. The review period is April 1, 1983 through March 31, 1984. There were no known shipments of this merchandise to the United States during the period, and there are no known unliquidated entries.

**Preliminary Results of the Review and Tentative Determination To Revoke in Part**

As a result of our review, we preliminarily determine that, as provided for in § 353.48(b) of the Commerce Regulations, a cash deposit of estimated antidumping duties of 6.40 percent shall be required on all shipments of Canadian steel reinforcing bars manufactured by Western Canada Steel Limited entered, or withdrawn from warehouse, for consumption on or

after the date of publication of the final results of this review.

Western Canada Steel Limited requested partial revocation of the finding and, as provided for in § 353.54(e) of the Commerce Regulations, Western Canada Steel Limited has agreed in writing to an immediate suspension of liquidation and reinstatement in the finding under circumstances as specified in the written agreement. Western Canada Steel Limited has not shipped this merchandise to the United States for more than ten years.

Therefore, we tentatively determine to revoke the antidumping finding on steel reinforcing bars from Canada with respect to Western Canada Steel Limited. If this partial revocation is made final, it will apply to all unliquidated entries of this merchandise exported by Western Canada Steel Limited entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice.

Interested parties may submit written comments to these preliminary results and tentative determination to revoke in part within 30 days of the date of publication of this notice and may request disclosure and/or a hearing within 10 days of the date of publication. Any hearing, if requested, will be held 45 days after the date of publication or the first workday thereafter. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing.

This administrative review, tentative determination to revoke in part, and notice are in accordance with sections 751(a)(1) and (c) of the Tariff Act of 1930 (19 U.S.C. 1675(a)(1), (c)) and §§ 353.53 and 353.54 of the Commerce Regulations (19 CFR 353.53, 353.54).

Alan F. Holmer,

Deputy Assistant Secretary for Import Administration.

April 19, 1985.

[FR Doc. 85-10200 Filed 4-25-85; 8:45 am]

BILLING CODE 3510-DS-M

**Minority Business Development Agency****Minority Business Development Center Program; Solicitation of Applications**

**AGENCY:** Minority Business Development Agency.

**ACTION:** Notice.



**SUMMARY:** The Minority Business Development Agency (MBDA) announces that it is soliciting applications under its Minority Business Development Center (MBDC) Program to operate a MBDC for a 3 year period, subject to available funds. The cost of performance for the first 11 months is estimated at \$171,417 for the project performance period of August 1, 1985 to June 30, 1986. The MBDC will operate in the Tucson Metropolitan Statistical Area (MSA). The first year cost for the MBDC will consist of \$145,704 in Federal funds and a minimum of \$25,713 in non-Federal funds (which can be a combination of cash, in-kind contribution and fees for services).

The I. D. Number for this project will be 09-10-85023-01.

The funding instrument for the MBDC will be a cooperative agreement and competition is open to individuals, nonprofit and for-profit organization, local and State governments, American Indian tribes and educational institutions.

The MBDC will provide management and technical assistance to eligible clients for the establishment and operation of businesses. The MBDC program is designed to assist those minority businesses that have the highest potential for success. In order to accomplish this, MBDA supports MBDC programs that can: coordinate and broker public and private sector resources on behalf of minority individuals and firms; offer them a full range of management and technical assistance; and serve as a conduit of information and assistance regarding minority business.

Applications will be judged on the experience and capability of the firm and its staff in addressing the needs of minority business individuals and organizations; the resources available to the firm in providing management and technical assistance; the firm's proposed approach to performing the work requirements included in the application; and the firm's estimated cost for providing such assistance. It is advisable that applicants have an existing office in the geographic region for which they are applying.

The MBDC will operate for a three (3) year period with periodic reviews culminating in annual evaluations to determine if funding for the project should continue. Continued funding will be at the discretion of MBDA based on such factors as the MBDC's satisfactory performance, the availability of funds, and Agency priorities.

A pre-application conference to assist all interested applicants will be held at the following address and time: Minority

Business Development Agency, U.S. Department of Commerce, 450 Golden Gate Avenue, Room 15015, San Francisco, California 94102. May 8, 1985 at 10:00 a.m.

Proposals are to be mailed to the following address: Minority Business Development Agency, U.S. Department of Commerce, San Francisco Regional Office, 450 Golden Gate Avenue, Box 36114, San Francisco, California 94102, 415/556-6734.

**Closing Date:** The closing date for applications is May 15, 1985. Applications must be postmarked on or before 5:00 pm—May 15, 1985.

**FOR FURTHER INFORMATION CONTACT:** Dr. Xavier Mena, Regional Director, San Francisco Regional Office.

#### **SUPPLEMENTARY INFORMATION:**

Questions concerning the preceding information, copies of application kits and applicable regulations can be obtained at the above address.

11.800 Minority Business Development (Catalog of Federal Domestic Assistance)

Xavier Mena,

Regional Director, San Francisco Regional Office.

April 22, 1985.

[FR Doc. 85-10131 Filed 4-25-85; 8:45 am]

BILLING CODE 3510-21-M

#### **Patent and Trademark Office**

##### **Interim Protection for Mask Works of Japanese Nationals, Domiciliaries and Sovereign Authorities; Changed Public Hearing Date**

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Rescheduling of public hearing date.

**SUMMARY:** The public hearing scheduled for May 6, 1985, in the Notice of Initiation of Proceeding, published on March 28, 1985, at 50 FR 12355-60 will be held on May 8, 1985, at 9:30 a.m. in the Commissioner's Conference Room, 11th Floor, Crystal Plaza Building 3, Room 11-C-20 instead of on May 6, 1985 as previously indicated.

**FOR FURTHER INFORMATION CONTACT:** Michael K. Kirk, Assistant Commissioner for External Affairs by telephone at (703) 557-3065 or by mail marked to his attention and addressed to Commissioner of Patents and Trademarks, Box 4, Washington, D.C. 20231.

Dated: April 22, 1985.

Donald J. Quigg,

Acting Commissioner of Patents and Trademarks.

[FR Doc. 85-10163 Filed 4-25-85; 8:45 am]

BILLING CODE 3510-16-M

#### **COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED**

##### **Procurement List 1985, Additions and Deletions**

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Additions to and deletions from procurement list.

**SUMMARY:** This action adds to and deletes from Procurement List 1985 commodities, military resale commodities and services to be provided by workshops for the blind and other severely handicapped.

**EFFECTIVE DATE:** April 26, 1985.

**ADDRESS:** Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.

**FOR FURTHER INFORMATION CONTACT:** C.W. Fletcher, (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** On August 3, August 31, November 9, November 26, December 7, and December 21, 1984, and January 4, February 1 and February 15, 1985, the Committee for Purchase from the Blind and Other Severely Handicapped published notices (49 FR 31126, 49 FR 34555, 49 FR 44789, 49 FR 46458, 49 FR 47980, 49 FR 49694, 50 FR 522, 50 FR 4726, 50 FR 6375 and 50 FR 6376) of proposed additions to and deletions from Procurement List 1985, October 19, 1984 (49 FR. 41195).

##### **Additions**

After consideration of the relevant matter presented, the Committee has determined that the commodities, military resale commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77 and 41 CFR 51-2.6.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered were:

- The actions will not result in any additional reporting, recordkeeping or other compliance requirements.
- The actions will not have a serious economic impact on any contractors for



the commodities, military resale commodities and services listed.

c. The actions will result in authorizing small entities to produce the commodities and military resale commodities and provide the services procured by the Government.

Accordingly, the following commodities, military resale commodities and services hereby added to Procurement List 1985.

#### Class 7340

Medium Weight Plastic Cutlery: 7340-00-NIB-0005 (Teaspoon) 7340-00-NIB-0006 (Soup spoon), 7340-00-NIB-0007 (Fork), 7340-00-NIB-0008 (Knife) (Requirements for the Army and Air Force Exchange Service)

#### Class 8340

Line, Tent (Manila): 8340-00-252-2268, 8340-00-252-2271, 8340-00-252-2273, 8340-00-252-2291, 8340-00-556-9689

#### Class 8465

Strap, Shoulder, Quick Release, Right Hand: 8465-01-078-9282

(Requirements for Mechanicsburg, Pennsylvania and Richmond, Virginia depots only)

#### Military Resale Item Nos. and Names

No. 521, Candles, Air Freshening, Fruit  
No. 522, Candles, Air Freshening, Holiday  
No. 523, Candles, Air Freshening, Floral  
No. 524, Candles, Air Freshening, Berry  
No. 525, Candles, Air Freshening, Forest  
No. 526, Candles, Air Freshening, Carnival  
No. 527, Candles, Air Freshening, Festival  
No. 528, Candles, Air Freshening, Herbal  
No. 529, Candles, Air Freshening, Assorted  
Scents with Holders

#### SIC 7331

Mailing Service, National Endowment for the Humanities, 1100 Pennsylvania Avenue NW., Room 202, Washington, D.C.

#### SIC 7349

Janitorial/Custodial, U.S. Court of Appeals, and Post Office, 7th and Mission Streets, San Francisco, California

Janitorial/Elevator Operator, Navy Yard Annex Buildings 159, 195E and 160, 2nd and M Street, SE., Washington, D.C.

Janitorial/Custodial, Indiana Dunes National Lakeshore, 1100 North Mineral Springs Road, Porter, Indiana

Janitorial/Custodial, for the following locations in Greenville, South Carolina: Kukowski-Donaldson Center, Perimeter Road, U.S. Army Reserve Center #1, 2201 Laurens Road, 3273rd U.S. Army Reserve Hospital, Suite B & C, 1003 Grove Road  
Janitorial/Custodial, Federal Executive Institute, Route #29 North Charlottesville, Virginia

#### SIC 7369

Commissary Shelf Stocking and Custodial, Myrtle Beach Air Force Base, South Carolina

#### Deletions

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77 and 41 CFR 51-2.6.

Accordingly, the following commodities are hereby deleted from Procurement List 1985:

#### Class 7210

Mattress, Innerspring: 7210-38-75-100, 7210-53-75-100

#### Class 7690

Decalcomania, ¾" Black: 7690-00-329-0538 For Official Use Only

Decalcomania, 1" Black: 7690-00-857-9572, Max Speed; 7690-00-857-9573, No Riders; 7690-00-857-9574, No Smoking; 7690-00-857-9575, U.S. Army

Decalcomania, 1" White Lusterless: 7690-00-857-9660, Max Speed; 7690-00-857-9662, No Smoking; 7690-00-857-9663, U.S. Army

Decalcomania, 1½" Black: 7690-00-857-9698, Max Speed; 7690-00-857-9699, No Riders; 7690-00-857-9700, No Smoking

Decalcomania, 1½" White Lusterless: 7690-00-857-9611, Max Speed; 7690-00-857-9612, No Riders; 7690-00-857-9613, No Smoking; 7690-00-857-9614, U.S. Army

Decalcomania, 2" Black: 7690-00-858-3403, No Smoking; 7690-00-858-3405, U.S. Army

Decalcomania, 2" White Lusterless: 7690-00-858-3365, No Smoking; 7690-00-858-3366, U.S. Army

Decalcomania, 3" Black: 7690-00-311-7272, No Smoking; 7690-00-311-7276, U.S. Army

Decalcomania, 3" White Lusterless: 7690-00-310-9227, No Smoking; 7690-00-310-9208, U.S. Army

Decalcomania, 4" Black: 7690-00-328-9507, Max Speed; 7690-00-328-9517, No Smoking

Decalcomania, 4" White Lusterless: 7690-00-329-0204, Max Speed; 7690-00-329-0205, No Smoking; 7690-00-329-0206, U.S. Army

Decalcomania, Numbers and Letters: 7690-1½"; 7690-2"; 7690-00-311-7128-3" White Lusterless Numeral "5"; 7690-4"

#### U.S. Postal Service Items

Decalcomania, P.S., 1" Lusterless White: P.S. #669-L, TP: P.S. #666-L, TP-40; P.S. #672-L, TP-45; P.S. #667-L, TP-50; P.S. #675-L, TP-65; P.S. #668-L, TP-70; P.S. #622-L, Lift Here

Decalcomania, P.S., 1" Gloss White: P.S. #635, No Riders

Decalcomania, P.S., 1½" Gloss White: P.S. #600, U.S. Army; P.S. #633, Max Speed; P.S. #636, No Riders

Decalcomania, P.S., 2" Gloss White: P.S. #607, U.S. Army.

C.W. Fletcher,

Executive Director.

[FR Doc. 85-10153 Filed 4-25-85; 8:45 am]

BILLING CODE 6820-33-M

#### Procurement List 1985, Proposed Additions and Deletion

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Proposed additions to and deletion from procurement list.

**SUMMARY:** The Committee has received proposals to add to and delete from Procurement List 1985 a commodities to be produced by and services to be provided by workshops for the blind and other severely handicapped.

Comments must be received on or before: May 29, 1985.

**ADDRESS:** Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.

**FOR FURTHER INFORMATION CONTACT:** C. W. Fletcher, (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77 and 41 CFR 51-2.6. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

#### Additions

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities and services listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities and services to Procurement List 1985, October 19, 1984 (49 FR 41195):

#### Class 8405

Poncho, Wet Weather: 8405-01-100-0976

#### Class 8465

Strap, Shoulder with Quick Release: 8465-00-269-0482

(Requirements for Richmond, Virginia Depot only)

#### SIC 7349

Janitorial/Custodial: Federal Building, 500 Quarrier Street, Charleston, West Virginia

#### SIC 7369

Commissary Shelf Stocking and Custodial: Patrick Air Force Base, Florida  
Commissary Shelf Stocking and Custodial: Fort Benjamin Harrison, Indianapolis, Indiana

#### Deletion

It is proposed to delete the following service from Procurement List 1985, October 19, 1984 (49 FR 41195):



## SIC 7699

Repair and Maintenance of Electric  
Typewriters; Railroad Retirement Board,  
844 N. Rush Street, Chicago, Illinois.

C.W. Fletcher,

*Executive Director.*

[FR Doc. 85-10154 Filed 4-25-85; 8:45 am]

BILLING CODE 6620-33-M

## DEPARTMENT OF DEFENSE

## Department of the Air Force

USAF Scientific Advisory Board;  
Meeting

April 24, 1985.

The USAF Scientific Advisory Board Ad Hoc Committee on Advanced Air Vehicle Surveillance and Warning Technologies will meet at the Pentagon, Room 5D982, Washington, D.C., on May 13, 1985, from 9:00 a.m. to 5:00 p.m. to review the committee's previous activities and to draft a report.

This meeting will involve classified defense matters listed in Section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at (202) 697-4648.

Norita C. Koritko,

*Air Force Federal Register, Liaison Officer.*

[FR Doc. 85-10213 Filed 4-25-85; 8:45 am]

BILLING CODE 3910-01-M

## Department of the Navy

Chief of Naval Operations, Executive  
Panel Advisory Committee, China Task  
Force; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee China Task Force will meet May 16-17, 1985, from 9 a.m. to 5 p.m. each day, at 2000 North Beauregard Street, Alexandria, Virginia. All sessions will be closed to the public.

The purpose of this meeting is to examine the broad policy issues related to maritime aspects of U.S.-P.R.C. relations. The entire agenda for the meeting will consist of discussions of key issues related to maritime policy aspects of U.S.-P.R.C. relations and related intelligence. These matters constitute classified information that is specifically authorized by Executive

order to be kept secret in the interest of national defense and is, in fact, properly classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact Lieutenant Thomas E. Arnold, Executive Secretary of the CNO Executive Panel Advisory Committee, 2000 North Beauregard Street, Room 392, Alexandria, Virginia 22311. Phone (703) 756-1205.

Dated: April 23, 1985.

William F. Roos, Jr.,

*Lieutenant, JAGC, U.S. Naval Reserve,  
Federal Register Liaison Officer.*

[FR Doc. 85-10164 Filed 4-25-85; 8:45 am]

BILLING CODE 3810-AE-M

Naval Research Advisory Committee;  
Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Naval Surface Weapons Center (NSWC) Review Team of the Naval Research Advisory Committee (NRAC) Panel on Laboratory Oversight will meet on May 13-14, 1985. The meeting will take place at Information Spectrum, Inc., 1745 South Jefferson Davis Highway, Arlington, Virginia, on May 13 and 14. Sessions of the meeting will commence at 8:30 A.M. and terminate at 5:00 P.M. on May 13 and 14, 1985. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to examine the scientific, technical and engineering health of NSWC. The agenda for the meeting will consist of Executive Sessions during which Review Team members will discuss presentations received and the preparation of a draft report. These discussions will contain classified information that is specifically authorized under criteria established by Executive order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive order. The classified and nonclassified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting contact: Commander M. B. Kelley, U.S. Navy, Office of Naval Research (Code 100N), 800 North Quincy Street, Arlington, VA 22217-5000, Telephone number (202) 696-4870.

Dated: April 23, 1985.

William F. Roos, Jr.,

*Lieutenant, JAGC, U.S. Naval Reserve,  
Federal Register Liaison Officer.*

[FR Doc. 85-10165 Filed 4-25-85; 8:45 am]

BILLING CODE 3810-AE-M

Navy Resale System Advisory  
Committee; Partially Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Navy Resale System Advisory Committee will meet on June 17, 1985, in the Four Seasons Olympic Hotel, 411 University Street, Seattle, Washington. The meeting will consist of two sessions: the first from 8:00 a.m. to 8:50 a.m.; and the second from 9:00 a.m. until 3:45 p.m. The purpose of the meeting is to examine policies, operations and organization of the Navy Resale System and to submit recommendations to the Secretary of the Navy. The agenda will include discussions of the organization of the Resale System, planning, financial management, merchandising, field support, and industrial relations.

The Secretary of the Navy has determined in writing that the public interest requires that the second session of the meeting be closed to the public because it will involve discussions of matters relating solely either to internal agency personnel rules and practices, or to trade secrets and confidential commercial or financial information. These matters fall within the exemptions listed in subsections 552b, (c)(2), (c)(4), and (c)(9)(B) of title 5, United States Code. Therefore, the second session will be closed to the public.

For further information concerning this meeting, contact: Commander R. F. Hendricks, SC, USN, Naval Supply Systems Command, NAVSUP 09B, Room 516, Crystal Mall, Building No. 3, Arlington, Virginia 22202, Telephone number: (202) 695-5457.

Dated: April 23, 1985.

William F. Roos, Jr.,

*Lieutenant, JAGC, U.S. Naval Reserve,  
Federal Register Liaison Officer.*

[FR Doc. 85-10166 Filed 4-25-85; 8:45 am]

BILLING CODE 3810-AE-M



## DEPARTMENT OF EDUCATION

## Office of Elementary and Secondary Education

## Magnet Schools Assistance Program for Fiscal Year 1985; Applications

**AGENCY:** Department of Education.

**ACTION:** Application Notice for New Projects under the Magnet Schools Assistance Program for Fiscal Year 1985.

Applications are invited for new projects under the Magnet Schools Assistance Program.

Authority for this program is contained in Title VII of the Education for Economic Security Act, Pub. L. 98-377, (20 U.S.C. 4051-4062).

The program issues awards to local educational agencies.

The purpose of the awards is to assist eligible local educational agencies in the planning, establishment, and operation of magnet schools that are a part of an approved desegregation plan. A "magnet school" is defined by the Act as a school or education center that offers a special curriculum capable of attracting substantial numbers of students of different racial backgrounds.

**Closing date for transmittal of applications:** Applications for new awards must be mailed or hand delivered by June 18, 1985.

**Applications delivered by mail:**

Applications sent by mail must be addressed to the U.S. Department of Education, Application Control Center, Attention: (CFDA No. 84.165) Washington, D.C. 20202.

An applicant must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.
- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
- (3) A dated shipping label, invoice, or receipt from a commercial carrier.
- (4) Any other proof of mailing acceptable to the U.S. Secretary of Education.

If an application is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service.

An applicant should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

An applicant is encouraged to use registered or at least first class mail. Each late applicant will be notified that its application will not be considered.

**Applications delivered by hand:**

Applications that are hand delivered must be taken to the U.S. Department of Education, Application Control Center, Room 5673, Regional Office Building #3, 7th and D Streets, SW., Washington, D.C.

The Application Control Center will accept hand-delivered applications between 8:00 a.m. and 4:30 p.m. (Washington, D.C. time) daily, except Saturdays, Sundays, and Federal holidays.

Applications that are hand delivered will not be accepted by the Application Control Center after 4:30 p.m. on the closing date.

**Program information:** Proposed regulations under the Magnet Schools Assistance Program were published in 49 FR 46169-46173 on November 23, 1984.

The proposed rules describe eligibility requirements for applicants, the types of projects that the Secretary assists, and the criteria to be used to evaluate applications.

Applications are being accepted based on the proposed regulations for the Magnet Schools Assistance Program. If any substantive changes are made in the final regulations for this program, applicants will be given an opportunity to revise or resubmit their applications.

**Intergovernmental review:** On June 24, 1983, the Secretary published in the Federal Register final regulations (34 CFR Part 79, published at 48 FR 29158-29168), implementing Executive Order 12372 entitled "Intergovernmental Review of Federal Programs." The regulations took effect September 30, 1983.

This program is subject to the requirements of the Executive Order and the regulations in 34 CFR Part 79. The objective of Executive Order 12372 is to foster an intergovernmental partnership and a strengthened federalism by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance.

The Executive Order—

- Allows States, after consultation with local officials, to establish their own process for review and comment on proposed Federal financial assistance;
- Increases Federal responsiveness to State and local officials by requiring Federal agencies to accommodate State and local views or explain why those views will not be accommodated; and
- Revokes OMB Circular A-95.

Transactions with nongovernmental entities, including State postsecondary educational institutions and federally recognized Indian tribal governments, are not covered by Executive Order

12372. Also excluded from coverage are research, development, or demonstration projects that do not have a unique geographic focus and are not directly relevant to the government responsibilities of a State or local government within that geographic area.

The Magnet Schools Assistance Program is a new program, and States have not made a determination as to whether it will be included or excluded from review under the State review process. Therefore, immediately upon receipt of this notice, applicants that are governmental entities, including local educational agencies, must contact the appropriate State single point of contact to find out about and to comply with the State's process under the Executive Order. Applicants proposing to perform activities in more than one State should contact, immediately upon receipt of this notice, the single point of contact for each State and follow the procedures established in those States under the Executive Order. A list containing the single point of contact for each State is included in the application package for this program.

All comments from State single points of contact and all comments from State, areawide, regional, and local entities must be mailed or hand delivered by August 19, 1985, to the following address:

The Secretary, U.S. Department of Education, Room 4181, (84.165) 400 Maryland Avenue, SW., Washington, D.C. 20202. Proof of mailing will be determined on the same basis as applications.

Please note that the above address is not the same address as the one to which the applicant submits its completed application. *Do not send applications to the above address.*

**Length of awards:** The proposed project period for an award may not exceed 24 months.

**Available funds:** The appropriation for this program for fiscal year 1985 is \$75,000,000. No eligible local educational agency may receive more than \$4,000,000 of that amount. However, the President has proposed budget rescissions to the Congress that may eliminate the funds for this program. The deadline in this notice will not be extended unless needed because of changes in the final regulations, and applicants should prepare and submit applications pending further notification.

**Application forms:** Application forms and program information packages are expected to be ready for mailing by May 3, 1985. They may be obtained by writing to the Division of Educational



Support, U.S. Department of Education, Room 2007, 400 Maryland Avenue, SW., Washington, D.C. 20202.

Applications must be prepared and submitted in accordance with the regulations, instructions, and forms included in the program information package. However, the program information is only intended to aid applicants in applying for assistance under this program.

Nothing in the program information package is intended to impose any paperwork, application content, reporting, or grantee performance requirements beyond those imposed under the statute and regulations.

Applicants are encouraged to limit the narrative section to a maximum of 30 pages. The Secretary strongly urges that applicants not submit information that is not requested.

(The application is approved by the Office of Management and Budget under OMB control number 1810-0516.)

**Applicable regulations:** The regulations applicable to this program include the following:

(a) Regulations governing the Magnet Schools Assistance Program as proposed to be codified in 34 CFR Part 280.

(b) Education Department General Administrative Regulations, (EDGAR) 34 CFR Parts 74, 75, 77, 78, and 79.

#### FOR FURTHER INFORMATION CONTACT:

For further information contact M. Patricia Goins, Division of Education Support, U.S. Department of Education, Room 2007, 400 Maryland Avenue, SW., Washington, D.C. 20202, Telephone: (202) 245-7965.

(20 U.S.C. 4051-4062)

(Catalog of Federal Domestic Assistance No. 84.165, Magnet Schools Assistance Program)

Dated: April 16, 1985.

William J. Bennett,

Secretary of Education.

[FR Doc. 85-10111 Filed 4-25-85; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Waste Management Activities for Groundwater Protection at the Savannah River Plant, Aiken, SC; Intent To Prepare an Environmental Impact Statement

**AGENCY:** Department of Energy.

**ACTION:** Notice of Intent to prepare an environmental impact statement on the implementation of hazardous, low-level radioactive, and mixed waste management activities for the protection of groundwater, human health, and the

environment at the Savannah River Plant near Aiken, South Carolina.

**SUMMARY:** The Department of Energy (DOE) announces its intent to prepare an environmental impact statement (EIS), in accordance with section 102(2)(C) of the National Environmental Policy Act (NEPA), as amended, to assess the potential environmental effects of modifying waste management activities for low-level radioactive, hazardous, and mixed wastes at SRP for the protection of groundwater, human health and the environment. These modifications will be based on compliance with applicable regulatory requirements. Waste management activities to be assessed in the EIS are:

1. The implementation of remedial and closure actions at active and inactive hazardous, low-level radioactive, and mixed waste sites.

2. The establishment of new onsite waste disposal facilities for hazardous, low-level radioactive, and mixed wastes.

3. Discharge of disassembly basin purge water from the C-, K-, and P-Reactors.

**Scoping:** DOE invites interested agencies, organizations, and the general public to submit comments or suggestions for consideration in the preparation of the EIS by May 28, 1985. Written comments and requests for additional information should be directed to Mr. C.G. Halsted, Jr., at the address below. Written comments postmarked after May 28, 1985, will be considered to the degree practicable. DOE will also hold two public scoping meetings at the locations and times indicated below:

1. Aiken, South Carolina on May 14, 1985, at 9:00 a.m. and 8:00 p.m. at the Odell Weeks Activity Center, 1700 Whiskey Road, Aiken, South Carolina 29801.

2. Beaufort, South Carolina on May 16, 1985, at 9:00 a.m. and 8:00 p.m. at the Ramada Inn-Beaufort, 3127 Boundary Street, Beaufort, South Carolina 29902.

Individuals desiring to make oral presentations at one of these meetings should notify Mr. Halsted at the address listed below as soon as possible after the appearance of this notice in the Federal Register so that the Department may arrange a schedule for the presentations. Persons who have not submitted a request to speak in advance may register to speak at the meetings before each meeting commences. They will be called on to present their comments as time permits. In order to assure that everyone who wishes to present oral comments has the opportunity to do so, five minutes will

be allotted to individuals, and ten minutes will be allotted to individuals representing groups. Comments received at these scoping meetings will also be considered in the preparation of the draft EIS. Transcripts of the scoping meetings will be prepared by DOE and will be available for inspection at the DOE Public Reading Room located at the University of South Carolina, Aiken Campus, University Library, 2nd Floor, University Parkway, Aiken, South Carolina, and the Freedom of Information Reading Room, Room 1E-190, Forrestal Building, 1000 Independence Avenue SW, Washington, DC.

**ADDRESS:** Written comments or suggestions on the scope of the EIS may be submitted to: Mr. C.G. Halsted, Jr., Assistant Manager for Health, Safety, and Environment, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, South Carolina 29802, (803) 725-1380.

Envelopes should be marked "Attention: EIS for Waste Management Activities for Groundwater Protection at SRP."

For general information on the DOE EIS process, please contact: Office of the Assistant Secretary for Policy, Safety, and Environment, U.S. Department of Energy, Attn: Ms. Carol M. Borgstrom (PE-252), Room 3C-092, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 252-4600.

#### Background Information

SRP is a major DOE installation established in the early 1950's for the production of nuclear materials for national defense. Operations at SRP generate a variety of chemically hazardous, radioactive, and mixed (hazardous and radioactive) wastes.

Waste management activities for groundwater protection have been studied and implemented on an ongoing basis at the Savannah River Plant since 1952. In 1977, an assessment of waste management operations at SRP (Final Environmental Impact Statement, Waste Management Operations, Savannah River Plant, ERDA-1537) was completed that resulted in the implementation of a waste management practices improvement program in accordance with DOE policies and standards. Included in this program are regular assessments and improvements to ongoing waste management practices, studies of improved waste management storage techniques, and studies designed to reduce the volume of waste being generated.



Recent regulatory requirements for groundwater protection—such as those enacted pursuant to the Resource Conservation and Recovery Act (RCRA), as amended, and the Comprehensive Environmental Response Compensation and Liability Act (CERCLA), as amended—have been adopted that require changes in the SRP waste management program. In response to these recent requirements and the Fiscal Year 1984 Supplemental Appropriations Act (Pub. L. 98-181 enacted in November 1983), DOE developed and submitted to Congress on June 13, 1984, the "Groundwater Protection Plan for the Savannah River Plant." This plan—which will be made available upon request—and its supporting appendices provide strategies, funding requirements, and schedules for remedial and closure actions at selected hazardous, low-level radioactive, and mixed SRP waste sites to ensure continued protection of groundwater, human health and the environment.

Projects are currently underway at SRP to comply with recently enacted RCRA and CERCLA regulatory requirements for groundwater protection and to protect public health and the environment. These projects include wastewater effluent treatment plants in the M-, F- and H-Areas, and TNX Area to discontinue use of seepage basins; a remedial action program in the M-Area to manage and control existing groundwater contamination; the removal of buried wastes and contaminated soil at the Chemicals, Metals, and Pesticides (CMP) pits; and continuation of the expanded program begun in 1981 to monitor and characterize groundwater quality and resources at SRP.

Further project decisions are necessary to comply with applicable regulatory requirements, including those pursuant to RCRA and CERCLA, and to meet DOE's continuing commitment to protect groundwater resources, human health and the environment; to perform actions necessary to comply with current applicable hazardous, low-level radioactive, and mixed wastes regulations; and to meet the commitments made during the L-Reactor environmental impact statement process. These project decisions are the subject of this EIS.

#### Alternatives

The Groundwater Protection Plan for the Savannah River Plant discusses remedial and closure measures for certain waste sites. Proposed new waste disposal facilities and the discharge of disassembly basin purge water from the C-, K-, and P-Reactors to seepage basins

are not covered in the Groundwater Protection Plan.

Alternatives for closure and remedial actions at existing hazardous, low-level radioactive, and mixed waste sites that will be evaluated in the EIS are:

1. Removal of waste to the extent practicable from existing waste sites, and implementation of cost-effective closure and remedial actions as required;
2. Removal of waste at selected existing waste sites, and implementation of cost-effective closure and remedial actions as required;
3. No removal of waste at existing waste sites, and implementation of cost-effective closure and remedial actions as required;
4. No action (no removal of waste at existing waste sites, and no closure or remedial actions).

Alternatives for new onsite hazardous, low-level radioactive, and mixed waste disposal facilities are:

1. Retrieval storage.
  2. Shallow land burial.
  3. Above ground disposal.
  4. A combination of retrievable storage, shallow land burial, and above ground disposal.
  5. No action (no new facilities).
- Pre-disposal techniques (e.g., incineration and compaction) for hazardous, low-level radioactive, and mixed wastes will be discussed in the EIS.

Alternatives for the discharge of disassembly basin purge water from the C-, K-, and P-Reactors are:

1. Detritiation.
2. Evaporation.
3. Direct discharge to onsite streams.
4. No action (continuation of discharge to seepage basins).

#### Identification of Environmental Issues

The following issues will be analyzed in this EIS. This list is not intended to be all inclusive; nor is it intended to be a predetermination of impacts.

1. Effects of remedial actions on groundwater quality and use.
2. Protection of human health and the environment.
3. Identification of "cleanup levels" at existing waste sites.
4. Dedication of selected waste sites.
5. Protection of groundwater including important aquifers for domestic and agricultural use.
6. Effects on endangered species, floodplain/wetlands, and archeological/historical sites.
7. Changes in surface water quality.
8. Interactive effects of remedial action measures.
9. Disposal of waste treatment material.

#### Referenced Documents

Members of the public may inspect the documents referenced in this notice during normal business hours at the DOE Public Reading Room located at the University of South Carolina, Aiken Campus, University Library, 2nd Floor, University Parkway, Aiken, South Carolina 29801.

Dated in Washington, DC, this 19th day of April, for the United States Department of Energy.

William A. Vaughan,

Acting Assistant Secretary for Policy, Safety, and Environment.

[FR Doc. 85-9977 Filed 4-25-85; 8:45 am]

BILLING CODE 6450-01-M

#### Civilian Radioactive Waste Management; Oak Ridge Operations; Monitored Retrievable Storage Analyses

**AGENCY:** Department of Energy.

**ACTION:** Program solicitation announcement.

**SUMMARY:** On April 25, 1985, the Department of Energy, Oak Ridge Operations Office in support of the Office of Civilian Radioactive Waste Management issued Program Solicitation No. DE-PS05-85OR21555 to the State of Tennessee requesting grant application(s). The purpose of the grant is to provide the host State with sufficient information, funds and technical assistance to understand the potential impacts of siting a Monitored Retrievable Storage (MRS) facility in its jurisdiction and, subsequently, to form an independent opinion regarding its acceptability. Upon receipt of the grant, the grantee may institute liaison activities with other concerned states, Indian tribes, and local governments as well as Federal representatives about MRS activities and related issues.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Nuclear Waste Policy Act of 1982 (Pub. L. 97-425) was signed into law by the President January 7, 1983 (see Federal Register Notification dated January 7, 1983). The major objectives of the Act are to provide for the development of repositories for the disposal of high-level radioactive waste and spent nuclear fuel, to establish a program of research, development, and demonstration regarding the disposal of high-level radioactive waste and spent fuel, and for other purposes related to disposal and storage of spent fuel and high-level radioactive waste. The Office of Civilian Radioactive Waste



Management was established to carry out provisions of the Act.

The Act established a schedule and step-by-step process by which the President, the Congress, the States, affected Indian tribes, the U.S. Department of Energy (DOE) and other Federal agencies must work together in the siting, construction and operation of geologic repositories for disposal of high-level radioactive waste generated by civilian nuclear reactors. This law has provided a mandate and, more important, a set of rules—including unprecedented collaboration among the Federal Government, the States and the public—for proceeding with the identification and selection of sites for a repository as well as for interim storage facilities in the event they are needed.

#### Principal Support Areas

Financial assistance will be provided the grantees in support of the following activities:

1. Obtaining technical assistance and evaluation services in determining any potential economic, social, public health and safety, and environmental impacts that are likely as a result of the development of a MRS facility in the State.
2. Conducting workshops within the State in order to familiarize local governments and/or other interested groups with the MRS as key program documents are developed and providing a forum for information transfer.
3. Scheduling and conducting technical assistance meetings with the State's technical contractors.
4. Discussing specific assumptions and analyses relating to the MRS facility and its siting with DOE. DOE shall provide access to its technical specialists and resources in furtherance of project objectives.

#### Eligibility and Limitations

Proposals from States other than the above-referenced prospective grantee are not requested.

The Department of Energy will consider applications from the State of Tennessee requesting grant support for up to three (3) sites. Grant support is expected to cover a performance period of 12 months.

#### Application Forms

Applications must be prepared and submitted in accordance with the instructions and forms included in the program solicitation.

#### Closing Date for Transmittal of Applications

Applications must be received by the Department of Energy by 4:00 p.m., May 27, 1985.

#### FOR FURTHER INFORMATION CONTACT:

All communications or questions regarding the business/administrative aspects of this program solicitation should be directed to: Mr. Walker K. Love, Procurement and Contracts Division, Department of Energy, Oak Ridge, TN 37830, Telephone Number: (615) 576-0791.

All communications or questions regarding the technical aspects of this program solicitation should be directed to: Mr. Peter J. Gross, MRS Office, Department of Energy, Oak Ridge, TN 37831, Telephone Number: (615) 576-6694.

(Catalog of Federal Domestic Assistance Number 81.065 Nuclear Waste Disposal Siting)

Effective Date: April 26, 1985.

Peter D. Dayton,

Director, Procurement and Contracts Division.

[FR Doc. 85-10198 Filed 4-25-85; 8:45 am]

BILLING CODE 6450-01-M

#### Announcement of Identification of Candidate Sites for a Proposal to Congress for a Monitored Retrievable Storage Facility and Availability of a Preliminary Analysis of the Need for and Feasibility of the Facility

**AGENCY:** Office of Civilian Radioactive Waste Management, DOE.

**ACTION:** Notice of announcement by the Office of Civilian Radioactive Waste Management (OCRWM) of the identification of three candidate sites for a proposal to Congress for a Monitored Retrievable Storage (MRS) facility. In addition, a document, "Need for and Feasibility of Monitored Retrievable Storage—A Preliminary Analysis" is available for review, and a report, "Screening and Identification of Sites for a Proposed Monitored Retrievable Storage Facility" is available for public distribution.

**SUMMARY:** OCRWM plans to study these sites for inclusion in a proposal to Congress for the construction of an MRS facility. The Department of Energy (DOE) plans to submit the proposal to Congress in January 1986.

Congress will then consider whether or not construction of an MRS facility will be authorized. The document now available for review will be used as a resource to develop the Needs and

Feasibility Study which will accompany the proposal to Congress.

The technical program to develop the proposal is being implemented by the DOE Operations Office in Richland, Washington. In order to facilitate communication and interactions with the potential host State, an MRS office is being established in the DOE Oak Ridge Operations Office in Oak Ridge, Tennessee.

#### FOR FURTHER INFORMATION CONTACT:

For Press information:

Mr. James Alexander, Public Information Office, Oak Ridge Operations Office, U.S. Department of Energy, P.O. Box E, Room 1012, Oak Ridge, TN 37831, (615) 576-0885  
—Ms. Ginger King, Office of Policy, Integration and Outreach, U.S. Department of Energy, RW-40, Washington, D.C. 20585, (202) 252-2835

For copies of documents:

—Mr. Ron Izatt, U.S. Department of Energy, Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, Richland, WA 99352  
—Mr. Peter Gross, Monitored Retrievable Storage Office, Oak Ridge Operations Office, P.O. Box E, U.S. Department of Energy, Oak Ridge, TN 37831, (615) 576-6694  
—Mr. James Carlson, Office of Storage and Transportation Systems, U.S. Department of Energy, RW-32, Washington, D.C. 20585, (202) 252-9433

#### Announcement

The U.S. Department of Energy (DOE) announced yesterday, April 25, 1985, that based upon its preliminary analysis it expects to propose to Congress in January 1986 an integrated nuclear waste disposal system which would include a Monitored Retrievable Storage (MRS) facility for consolidating, packaging, handling and temporary storage of spent nuclear fuel prior to disposal in deep geologic repositories. Disposal of nuclear waste is scheduled to begin in 1998.

The Nuclear Waste Policy Act of 1982 (the Act) established Federal policy and responsibility for the management of commercial spent nuclear fuel and high-level radioactive waste. The primary focus of the Act is the construction of a geologic repository by 1998. The Act also directed DOE to examine monitored retrievable storage as an option for storage of spent fuel. The Act clearly states that permanent disposal of high-level radioactive waste and spent nuclear fuel in a geologic repository should proceed in any case.



The Act charges DOE with development of a system to dispose of the nation's nuclear waste. It is expected that 43,000 metric tons of spent nuclear fuel will be awaiting disposal in 1998. The need and feasibility preliminary analysis has concluded that a waste system which integrates deep geologic repositories for disposal with an MRS to consolidate, package and, if necessary, temporarily store the waste would be the best strategy to serve the nation's needs.

It should be noted that Congress has not authorized construction of an MRS facility. The MRS was seen by Congress as an option for the long-term storage of nuclear wastes. The Act specifically directs the Department to prepare a proposal for construction of one or more MRS facilities and submit this proposal to the Congress. The proposal is to include a recommendation of the preferred site for an MRS. Proposal documentation will include plans for funding, constructing, operating and integrating MRS facilities, and site specific designs and cost estimates. An environmental assessment which compares the advantages and disadvantages of the various combinations of proposed sites and facility designs must accompany the proposal. In addition, a Needs and Feasibility Study will also accompany the proposal. While the Act requires that this be done by June 1, 1985, the Department will not be able to meet that deadline. The proposal is expected to be ready for submittal by January 15, 1986.

If approved by Congress, the MRS facility would begin operation in the 1996-1997 timeframe as an integral part of the federal nuclear waste management system. DOE expects to propose that spent nuclear fuel from the nation's commercial nuclear power plants be transported to an MRS facility for preparation and packaging, prior to delivery to a repository for final disposal. An MRS facility could provide temporary storage, with room for expansion if additional storage is needed.

With a large majority of the nation's commercial nuclear reactors located in the eastern, southern and midwestern portions of the United States, locating an MRS facility at any one of the candidate MRS sites would significantly reduce spent fuel transportation impacts. With most of the spent fuel being shipped to a centrally located MRS, the largest number of shipments will be shorter in duration than they would if travelling directly to a

repository. The majority of shipments to an MRS are expected to be by truck. Once at the MRS, the spent fuel would be consolidated and repackaged. Shipments from the MRS to the repository could then be made by dedicated train. Since rail shipments can carry much heavier loads than truck shipments, fewer rail shipments would be needed between the MRS and the repository than truck shipments. This would significantly reduce the number of long distance shipments and transportation impacts.

The three MRS candidate sites, which include a preferred and two alternatives, have been identified by DOE following a screening and evaluation process. This has been documented in a report titled "Screening and Identification of Sites for a Proposed Monitored Retrievable Storage Facility" (DOE/RW-0023) which is available for public distribution. The preferred candidate site is located at the cancelled Clinch River Breeder Reactor site; the two alternative candidate sites are located on the DOE Oak Ridge Reservation and at the cancelled Tennessee Valley Authority Hartsville Nuclear Plant site. These sites will be further evaluated and two alternative facility designs will be prepared for each site. Evaluation of the six design/site combinations will accompany the DOE proposal to Congress.

It is the intent of the Department to prepare a proposal which will allow Congress to make an informed decision regarding the MRS and the integrated system; provide full opportunity for affected parties to express their views during proposal development; and, provide the States, Indian Tribes and public an opportunity to gain an understanding of the proposal which will allow their informed participation in the Congressional decision-making process.

The DOE is prepared to work closely with the States, Indian Tribes and public to prepare the best supporting documentation possible for the proposal to be delivered to Congress in January 1986. The Department's mission is to provide high quality technical documents for use in the Congressional decision-making process. It is DOE's intent to provide information and technical assistance to give interested parties an opportunity to gain an understanding of the impacts of siting an MRS and, subsequently, to form independent opinions regarding MRS acceptability.

Workshops, technical briefings and public meetings are methods that could

be employed to involve interested States, Indian Tribes and the public in the MRS process. The Department believes it is important to receive the benefit of public feedback from diverse viewpoints during preparation of the proposal and its supporting documentation. The views expressed at such workshops, briefings and meetings could be summarized in proceedings reports and forwarded to Congress with the proposal for consideration during its deliberations.

An environmental assessment which evaluates the relative advantages and disadvantages of the design/site combinations will be prepared in the coming months to accompany the MRS proposal to Congress. The Act states that this environmental assessment is to be based on available information. The DOE solicits the help of States, affected Indian Tribes and the public to provide available information which may be useful in preparation of the environmental assessment. It is requested that available information be provided no later than July 1, 1985, so that the information may be considered in development of the environmental assessment. Such information should be sent to:

Mr. Ron Izatt, U.S. Department of  
Energy, Richland Operations Office,  
825 Jadwin Avenue, P.O. Box 550,  
Richland, WA 99352

In addition to the environmental assessment, a Needs and Feasibility Study which will consider several MRS options, including the "No MRS" option, will accompany the proposal to Congress. The preliminary analysis has been made available for public review (DOE/RW-0022) will be used as a resource to develop the Needs and Feasibility Study. (Copies of the document may be obtained from Mr. Ron Izatt, Mr. Peter Gross or Mr. James Carlson at the addresses listed above.) Any person wishing to do so, should submit their views in writing to Mr. Carlson, at the address listed above by July 1, 1985. This cutoff date is necessary so that public views may be considered in developing the Needs and Feasibility Study.

Effective Date: April 28, 1985.

Ben C. Rusche,

Director, Office of Civilian Radioactive  
Waste Management.

[FR Doc. 85-10199 Filed 4-25-85; 8:45 am]

BILLING CODE 6450-01-M



**Economic Regulatory Administration**

[Docket No. ERA-FC-84-021; OFP Case No. 61051-9257-20-24]

**Applied Energy Sciences, Inc.; Order Granting Exemption From Prohibitions**

**AGENCY:** Economic Regulatory Administration, Department of Energy.

**ACTION:** Order granting to Applied Energy Sciences, Inc., exemption from prohibitions of the Powerplant and Industrial Fuel Use Act of 1978.

**SUMMARY:** The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice that it has granted a permanent cogeneration exemption from the prohibitions of Title II of the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 *et seq.* ("FUA" or "the Act"), to Applied Energy Sciences, Inc. (AES Geismar of "the petitioner"), of Geismar, Louisiana. The permanent cogeneration exemption permits the use of natural gas as the primary energy source for a planned AES Geismar facility located in Geismar, Louisiana. The facility will include one combustion turbine generator, one heat recovery steam generator, one steam turbine and other support equipment. The cogeneration facility will produce approximately 280,000 lb/hr of process steam and 123,400 kilowatts of electrical power. The final exemption order and detailed information on the proceeding are provided in the

**Supplementary Information** section, below.

**DATE:** The order shall take effect on June 25, 1985.

The public file containing a copy of the order, other documents, and supporting materials on this proceeding is available upon request through DOE, Freedom of Information-Reading Room, 1000 Independence Avenue SW., Room 1E-190, Washington, D.C. 20585, Monday through Friday, 9:00 a.m. to 4:00 p.m., except Federal holidays.

**FOR FURTHER INFORMATION:**

Frank Duchaine, Office of Fuels Programs, Economic Regulatory Administration, 1000 Independence Avenue, SW., Room GA-0456, Washington D.C. 20585, Telephone (202) 252-8233

Steven E. Ferguson, Office of the General Counsel, Department of Energy, Forrestal Building, Room 6A-113, 1000 Independence Avenue, SW., Washington D.C. 20585, Telephone (202) 252-6947

**SUPPLEMENTARY INFORMATION:** The proposed cogeneration facility will include one Westinghouse 501-D5 gas

turbine/generator or equivalent as the fuel burning unit. The heat recovery steam generator will be unfired, except during emergency conditions when the gas turbine is not operating. Natural gas will be the only fuel used and there will be no emergency standby fuel.

Under normal operating conditions the capacity of the proposed combined cycle plant will be approximately 280,000 lb/hr of process steam and 123 MWe (net) of electrical power at average ambient air conditions. Under minimum process steam conditions the capacity of the plant will be approximately 120,000 lb/hr of process steam and 140 MWe (net) of electrical power at average ambient air conditions. Under maximum process steam conditions the capacity of the plant will be approximately 340,000 lb/hr of process steam and 117 MWe (net) of electrical power at average ambient air conditions.

The primary purpose of the proposed facility is to provide process steam for use by the adjacent Uniroyal Chemical Plant. Electric power will also be generated for sale to Gulf States Utilities as a secondary benefit derived from efficient facility operation.

**Basis for Permanent Exemption Order**

The permanent exemption order is based upon evidence in the record including AES Geismar's certification to ERA, in accordance with § 503.37(a)(1), that:

1. The oil or natural gas to be consumed by the cogeneration facility will be less than that which would otherwise be consumed in the absence of the proposed powerplant, where the calculation of savings is in accordance with 10 CFR § 503.37.(a)(1)(i); and
2. The use of a mixture of natural gas and coal or oil and coal in the cogeneration facility will not be technically feasible, in accordance with 10 CFR § 503.37(a)(1)(ii).

**Procedural Requirements**

In accordance with the procedural requirements of section 701(c) of FUA and 10 CFR § 501.3(b), ERA published its Notice of Acceptance of Petition and Availability of Certification in the **Federal Register** on December 18, 1984 (49 FR 35221), commencing a 45-day public comment period.

A copy of the petition was provided to the Environmental Protection Agency for comments as required by section 701(f) of the Act. During the comment period, interested persons were afforded an opportunity to request a public hearing. The comment period closed on February 1, 1985; no comments were received and no hearing was requested.

**NEPA Compliance**

After review of the petitioner's environmental impact analysis, together with other relevant information, ERA has determined that the granting of the requested exemption does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA).

**Order Granting Permanent Cogeneration Exemption**

Based upon the entire record of this proceeding, ERA has determined that AES Geismar has satisfied the eligibility requirements for the requested permanent cogeneration exemption, as set forth in 10 CFR § 503.37. Therefore, pursuant to section 212(c) of FUA, ERA hereby grants a permanent cogeneration exemption to AES Geismar to permit the use of natural gas as the primary energy source for its cogeneration facility in Geismar, Louisiana.

Pursuant to section 702(c) of the Act and 10 CFR § 501.69, any person aggrieved by this order may petition for judicial review thereof at any time before the 60th day following the publication of this order in the **Federal Register**.

Issued in Washington, D.C., on April 18, 1985.

**Robert L. Davies,**

Director, Coal & Electricity Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 85-10127 Filed 4-25-85; 8:45 am]

**BILLING CODE 6450-01-M**

**Western Area Power Administration****California-Oregon Transmission Project; Intent To Conduct Public Scoping Meetings**

**AGENCY:** U.S. Department of Energy, Western Area Power Administration.

**ACTION:** Notice of intent to conduct public scoping meetings.

**SUMMARY:** In accordance with the National Environmental Policy Act of 1969 (NEPA), Western Area Power Administration (Western), Department of Energy (DOE), and the Transmission Agency of Northern California (Agency) will jointly conduct a series of public meetings to determine the scope of environmental issues to be addressed during the preparation of the environmental impact statement/environmental impact report (EIS/EIR) for the California-Oregon third 500-kilovolt (kV) alternating current (AC)



transmission line. This transmission line is proposed to extend from the California-Oregon border to the Central Valley of California east of the San Francisco Bay Area. Western and the Agency will coordinate the environmental analysis and review of the project with the Bonneville Power Administration; U.S. Department of Agriculture, Forest Service (USFS); and the California Public Utilities Commission.

#### Background

Since the Notice of Intent to prepare an EIS for the subject project was published in the Federal Register (Vol. 49, No. 217, page 44546, November 7, 1984), new developments have occurred. Western will represent DOE as the lead Federal agency in the preparation of the EIS. The USFS will be a cooperating agency.

The Agency has been designated as the Project Manager and lead State agency in accordance with the California Environmental Quality Act, and will be responsible for preparing an EIR. The California Public Utilities Commission will have the role of a responsible State agency in the process due to the participation of California investor-owned utilities. To reduce time and costs, the Federal and State lead agencies have agreed to combine efforts and prepare a joint EIS/EIR.

The project will be owned by municipal and investor-owned utilities in California and Western. The project participants include: (1) Municipal utilities represented by the Agency, which include the cities of Alameda, Biggs, Gridley, Healdsburg, Lodi, Lompoc, Palo Alto, Redding, Roseville, Santa Clara, and Ukiah, the Modesto and Turlock Irrigation Districts, the Sacramento Municipal Utility District, and the Plumas-Sierra Rural Electric Cooperative; (2) Investor-owned utilities including Pacific Gas and Electric Company (PG&E), San Diego Gas and Electric Company, and Southern California Edison; (3) the Southern California Public Agencies, which include the cities of Anaheim, Azusa, Banning, Colton, Glendale, Vernon, and Riverside; and (4) the Western Area Power Administration. The California Department of Water Resources also has an option to participate starting in the year 2005. The proposed line would provide approximately 1,600 megawatts of power transmission capacity to the project participants.

The proposed facilities would include a new 500-kV transmission line which would begin at a northern terminal in southern Oregon and extend to the vicinity of Redding, California. From

Redding to Tracy, California, an existing 230-kV line may be upgraded to 500-kV, or a new line may be built if it is shown to be environmentally and economically preferable. A new 500-kV transmission line would also be constructed between Western's Tracy Substation and PG&E's Tesla Substation, a distance of about 8 miles. A new 500-kV line may be built between the Round Mountain and Redding areas. The entire project would include approximately 350 miles of 500-kV line and three new or upgraded substations. The purpose of the project is to permit sales of power from the Pacific Northwest to California, to displace relatively more expensive oil- and gas-generated power, and to provide more reliability to the existing transmission system. The purpose of the environmental studies is to identify the potential environmental impacts and to identify possible routes for the transmission lines and sites for the new substations which minimize impacts to the environment.

#### Meetings

Western and the Agency will jointly conduct a series of public scoping meetings during 1985 in California and Oregon. The purposes of the meetings are: (1) To inform private citizens, organizations, Federal, State, and local agencies, and public and private utilities of the proposed project; and (2) to receive comments and information that will assist in identifying the environmental issues to be addressed in the EIS/EIR. The meetings will be conducted on the dates and at the locations listed below.

#### Northern Schedule

- May 13, 1985, 7:30 p.m., City Council Chambers, 1313 California Street, Redding, CA
- May 14, 1985, 7:30 p.m., City Council Chambers, 1175 East Main Street, Ashland, OR
- May 15, 1985, 9:00 a.m., Board of Supervisors Chambers, 526 West Sycamore, Willows, CA (combined w/ Planning Commission meeting)
- May 15, 1985, 7:30 p.m., Multipurpose Room, Newell Elementary School, Highway 139, Newell, CA (9 miles south of Tulelake)
- May 16, 1985, 7:30 p.m., American Legion Hall, Highway 299 at Long Street, Fall River Mills, CA
- May 21, 1985, 7:30 p.m., City Council Chambers, 550 Main Street, Weed, CA
- May 22, 1985, 7:30 p.m., Board of Supervisors' Chambers, 633 Washington Street, Red Bluff, CA
- May 23, 1985, 1:30 p.m., Airport Sheraton Inn, 8235 Northeast Airport Way, Portland, OR

#### Southern Schedule

- May 13, 1985, 7:30 p.m., City Hall Auditorium, 425 Webster Street, Colusa, CA
- May 14, 1985, 7:30 p.m., Board of Supervisors Chambers, 25 County Center Drive, Oroville, CA
- May 15, 1985, 7:30 p.m., Yolo County Planning Commission Meeting Room, 292 West Beamer Street, Woodland, CA
- May 16, 1985, 7:30 p.m., City Council Chambers, 1201 Civic Center Boulevard, Yuba City, CA
- May 20, 1985, 7:30 p.m., Board of Supervisors Chambers, Courthouse, 580 Texas Street, Fairfield, CA
- May 21, 1985, 7:30 p.m., Tracy Community Center, 300 East Tenth Street, Tracy, CA
- May 22, 1985, 7:30 p.m., Delta Community Services Center, 730 Third Street, Brentwood, CA
- May 23, 1985, 1:00 p.m., Atlantis Lounge, Campus Village Community Center, University of California at Irvine, Irvine, CA

#### FOR FURTHER INFORMATION CONTACT:

Persons wanting to be included on the mailing list to receive relevant information as the project progresses or wanting further information about the scoping meetings, may contact: Nancy Weintraub, Environmental Manager, Sacramento Area Office, Western Area Power Administration, 1825 Bell Street, Sacramento, CA 95825, (916) 440-3115, FTS 448-3115. Lawrence T. Klein, Project Director, California-Oregon Transmission Project, P.O. Box 660970, Sacramento, CA 95866 (916) 924-3995

Issued at Golden, Colorado: April 17, 1985.

William H. Clagett,

Administrator.

[FR Doc. 85-10128 Filed 4-25-85; 8:45 am]

BILLING CODE 6450-01-M

#### ENVIRONMENTAL PROTECTION AGENCY

[OPTS-59186A; FRL-2822-6]

#### Certain Chemicals; Approval of Test Marketing Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces EPA's approval of an application for a test marketing exemption (TME) under section 5(h)(6) of the Toxic Substances Control Act (TSCA), TME-85-28. The test marketing conditions are described below.



**EFFECTIVE DATE:** April 12, 1985.

**FOR FURTHER INFORMATION CONTACT:** Candy Brassard, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-609C, 401 M Street SW., Washington, DC 20460 (202-382-3394).

**SUPPLEMENTARY INFORMATION:** Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use and disposal of the substances for test marketing purposes will not present any unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present any unreasonable risk of injury.

EPA hereby approves TME-85-28. EPA has determined that test marketing of the new chemical substance described below, under the conditions set out in the TME application, and for the time period and restrictions (if any) specified below, will not present any unreasonable risk of injury to health or the environment. Production volume, use and the number of customers must not exceed that specified in the application. All other conditions and restrictions described in the application and in this notice must be met.

The following additional restrictions apply to TME-85-28. A bill of lading accompanying each shipment must state that use of the substance is restricted to that approved in the TME. In addition, the Company shall maintain the following records until five years after the dates they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. The applicant must maintain records of the quantity of the TME substance produced and must make these records available to EPA upon request.
2. The applicant must maintain records of the dates of shipment to each customer and the quantities supplied in each shipment, and must make these records available to EPA upon request.
3. The applicant must maintain copies of the bill of lading that accompanies each shipment of the TME substance.
4. The applicant must maintain the following information on disposal of the

TME substance: dates waste material is disposed of, location of disposal sites, volume of any disposed solid material, estimated volume of any aqueous wastes containing the TME substance, and method of disposal.

#### **TME 85-28**

*Dated of Receipt:* February 27, 1985.

*Notice of Receipt:* March 8, 1985 (50 FR 9509).

*Applicant:* CP Chemicals, Inc.

*Chemical:* (S) Stannous (Tin 2+) methanesulfonate.

*Use:* (S) Component in electroplating bath.

*Production Volume:* 4,545 Kilograms.

*Number of Customers:* Six.

*Worker Exposure:* Manufacture: A total of 3 workers at 1 site for 1 to 2 hours per day, 20 days per year. Use: a total of 6 workers at up to 6 sites for 2 to 8 hours per day, 7 to 28 days per year.

*Test Marketing Period:* One year.

*Commencing on:* April 12, 1985.

*Risk Assessment:* EPA identified no significant concerns for health effects. Therefore, the test market substance will not present any unreasonable risk of injury to health. The Agency did identify potential adverse effects on aquatic organisms. However, since the low releases from manufacture and use will be sent to a POTW or on-site treatment facility, the test market substance will not pose any unreasonable environmental risk.

*Additional Restrictions:* The applicant and its customers will be required to send the releases from manufacture and/or use to a POTW or an on-site treatment facility.

*Public Comments:* None.

The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to health or the environment.

*Dated:* April 12, 1985.

**Don R. Clay,**

*Director, Office of Toxic Substances.*

[FR Doc. 85-9596 Filed 4-25-85; 8:45 am]

**BILLING CODE 6560-SO-M**

[OPTS-59192; FBL-2825-9]

#### **Adduct of Polymer 4,4'-Phenylmethane Diisocyanate and Hydroxyester of Terephthalic Acid; Test Marketing Exemption Application**

**AGENCY:** Environmental Protection Agency (EPA).

#### **ACTION:** Notice.

**SUMMARY:** EPA may upon application exempt any person from the premanufacture notification requirements of section 5 (a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice, issued under section 5(h)(6) of TSCA, announces receipt of one application for an exemption, provides a summary, and requests comments on the appropriateness of granting the exemptions.

**DATE:** Written comments by May 13, 1985.

**ADDRESS:** Written comments, identified by the document control number "[OPTS-59192]" and the specific TME number should be sent to: Document Control Officer (TS-973), Chemical Information Branch, Information Management Division, Office of Toxic Substances, Environmental Protection Agency, Rm. E-4201, 401 M Street SW., Washington, DC 20460 (202-382-3532).

**FOR FURTHER INFORMATION CONTACT:** Wendy Cleland-Hamnett, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street SW., Washington, DC 20460 (202-382-3725).

**SUPPLEMENTARY INFORMATION:** The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the TME received by EPA. The complete non-confidential document is available in the Public Reading Room E-107 at the above address.

#### **T 85-40**

*Close of Review Period:* May 26, 1985.  
*Manufacturer:* Confidential.

*Chemical:* (G) Adduct of polymeric 4,4'-phenylmethane diisocyanate and hydroxyester of terephthalic acid.

*Use/Production:* (G) Insulation. Prod. range: Confidential.

*Toxicity Data:* No data submitted.

*Exposure:* Manufacture: Dermal a total of 1 worker, up 4 hrs/batch, at 48 manhours/yr.

*Environmental Release/Disposal:* No data submitted.



Dated: April 22, 1985.

V. Paul Fuschini,  
Acting Director, Information Management  
Division.

[FR Doc. 85-10150 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51568; FRL-2825-8]

### Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection  
Agency (EPA).

ACTION: Notice.

**SUMMARY:** Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of the final rule published in the *Federal Register* of May 13, 1983 (48 FR 21722). This notice announces receipt of twenty-one PMNs and provides a summary of each.

#### DATES: Close of Review Period:

P 85-800 and 85-801—July 10, 1985.  
P 85-802 and 85-803—July 13, 1985.  
P 85-804, 85-805, 85-806, 85-807, 85-808, 85-809 and 85-810—July 14, 1985.  
P 85-811, 85-812, 85-813, 85-814, 85-815, 85-816 and 85-817—July 15, 1985.  
P 85-818, 85-819, and 85-820—July 17, 1985.

#### Written comments by:

P 85-800 and 85-801—June 10, 1985.  
P 85-802 and 85-803—June 13, 1985.  
P 85-804, 85-805, 85-806, 85-807, 85-808, 85-809 and 85-810—June 14, 1985.  
P 85-811, 85-812, 85-813, 85-814, 85-815, 85-816 and 85-817—June 15, 1985.  
P 85-818, 85-819, and 85-820—June 16, 1985.

**ADDRESS:** Written comments, identified by the document control number "[OPTS-51568]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Chemical Information Branch, Information Management Division, Office of Toxic Substances, Environmental Protection Agency, Rm. E-201, 401 M Street SW., Washington, DC 20460 (202-382-3532).

#### FOR FURTHER INFORMATION CONTACT:

Wendy Cleland-Hamnett,  
Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street SW., Washington, DC 20460 (202-382-3725).

**SUPPLEMENTARY INFORMATION:** The following notice contains information

extracted from the non-confidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete non-confidential document is available in the Public Reading Room E-107 at the above address.

#### P 85-800

**Manufacturer.** Olin Corporation.  
**Chemical.** (G) Sodium salt of polycarboxylic acid.

**Use/Production.** (S) Industrial and commercial surfactant—general industrial cleaning. Prod. range: Confidential.

**Toxicity Data.** Acute oral: >5.0 g/kg; Acute dermal: >2.0 g/kg; Irritation: Skin—Mild or slight, Eye—Mild; Ames Test: Not determined; Skin sensitization: Sensitizer.

**Exposure.** Manufacture: Dermal, a total of 5 workers, up to 1 hr/da, up to 200 da/yr.

**Environmental Release/Disposal.** Greater than 2 kg/da to greater than 2,500 kg/yr released to water with greater than 4 kg/da to land.

Disposal by incineration, landfill and activated sludge treatment plants.

#### P 85-801

**Manufacturer.** Confidential.

**Chemical.** (G) adduct of polymeric 4,4'-phenylmethane diisocyanate and hydroxyester of terephthalic acid.

**Use/Manufacture.** (G) Insulation. Prod. range: Confidential.

**Toxicity Data.** No data submitted.

**Exposure.** Confidential.

**Environmental Release/Disposal.** No release. Disposal by waterway.

#### P 85-802

**Manufacturer.** Confidential.

**Chemical.** (G) Functionalized styrene methacrylic polymer.

**Use/Production.** (G) Component for industrial specialty coatings. Prod. range: 40,000–252,000 kg/yr.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture and processing: Dermal, a total of 58 workers, up to 8 hrs/da, up to 32 da/yr.

**Environmental Release/Disposal.** 5 to 135 kg/batch released to land. Disposal by incineration and landfill.

#### P 85-803

**Manufacturer.** The Minnesota Mining and Manufacturing Company.

**Chemical.** (G) 4,4'-phenylmethane diisocyanate adduct of polyether polyol.

**Use/Production.** (S) Commercial primer for repair of urethane foam roof coating. Prod. range: Confidential.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture: Dermal, a total of 2 workers/shift up to 2 hrs/da, up to 30 da/yr.

**Environmental Release/Disposal.** 71 kg/batch released. Disposal by incineration.

#### P 85-804

**Manufacturer.** Eastman Kodak Company.

**Chemical.** (S) 2-Methyl-6-quinolinamine hydrochloride.

**Use/Production.** (G) Chemical intermediate. Prod. range: 2–4 kg/yr.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture and use: Dermal, inhalation and ocular, a total of 2 workers, up to 0.4 hr/da, up to 3 da/yr.

**Environmental Release/Disposal.** Less than 0.01 kg/batch incinerated.

#### P 85-805

**Manufacturer.** Eastman Kodak Company.

**Chemical.** (S) 2-Methyl-6-quinolinamine.

**Use/Production.** (G) Chemical intermediate. Prod. range: 2–3 kg/yr.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture and use: Dermal, inhalation and ocular, a total of 4 workers, up to 1.1 hr/da, up to 3 da/yr.

**Environmental Release/Disposal.** Less than 0.5 kg/batch incinerated.

#### P 85-806

**Manufacturer.** Eastman Kodak Company.

**Chemical.** (S) 2-Methyl-6-nitroquinoline.

**Use/Production.** (G) Chemical intermediate. Prod. range: 2.5–4.0 kg/yr.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture and use: Dermal, inhalation and ocular, a total of 6 workers, up to 1.3 hr/da, up to 4 da/yr.

**Environmental Release/Disposal.** Less than 0.2 kg/batch incinerated.

#### P 85-807

**Manufacturer.** Confidential.

**Chemical.** (G) Polyperester of ketopolycyclic polyacid.

**Use/Production.** (G) A formulation component for open non-dispersive use. Prod. range: 50–250 kg/yr.

**Toxicity Data.** No data submitted.

**Exposure.** Manufacture: Dermal, a total of 18 workers.

**Environmental Release/Disposal.** 0.05 to 0.10 kg/batch released to land. Disposal by landfill

#### P 85-808

**Manufacturer.** Confidential.

**Chemical.** (G) Polyester resin.



*Use/Production.* (S) Electrical insulation intermediate. Prod. range: Confidential.

*Toxicity Data.* No data submitted.

*Exposure.* Confidential.

*Environmental Release/Disposal.* Confidential.

#### P85-809

*Manufacturer.* Confidential.

*Chemical.* (G) Terpolymer with styrene and methyl methacrylate.

*Use/Production.* (G) Industrial coating polymer. Prod. range: 40,000-252,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture and processing: Dermal, a total of 58 workers, up to 8 hrs/da, up to 32 da/yr.

*Environmental Release/Disposal.* 5 to 135 kg/batch released to land. Disposal by incineration and landfill.

#### P85-810

*Manufacturer.* Confidential.

*Chemical.* (S) (Z)-1-bromo-3-hexene.

*Use/Production.* (G) Chemical synthetic intermediate-structure use. Prod. range: Confidential.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture and use: Dermal, a total of 6 workers, up to 2 hr/da, up to 5 da/yr.

*Environmental Release/Disposal.* 0.020 to 0.17 kg/batch released to air. Disposal by incineration.

#### P85-811

*Manufacturer.* Confidential.

*Chemical.* (G) Polyurethane polyol.

*Use/Production.* (G) Industrially applied coating product. Prod. range: 225,000-500,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture and processing: Dermal, a total of 29 workers, up to 8 hrs/da, up to 260 da/yr.

*Environmental Release/Disposal.* 4 to 180 kg/batch released to land. Disposal by incineration and landfill.

#### P85-812

*Importer.* Confidential.

*Chemical.* (G) 2-[3',5'-disubstituted-2'-hydroxyphenyl]benzotriazole.

*Use/Import.* (G) Open, non-dispersive use; additive for coatings. Import range: Confidential.

*Toxicity Data.* Acute oral: Male and female—>5,000 mg/kg; Acute dermal: Male and female—>2,000 mg/kg; Irritation: Skin Non-irritant, Eye—Non-irritant; Ames Test: Non-mutagenic; Skin sensitization: Strong sensitizer; Ready biodegradability test: Not readily biodegradable; LC<sub>50</sub> 96 hr (Bluegill sunfish): 3.8 mg/l; LC<sub>50</sub> 96 hr (Bluegill sunfish): 1.8 mg/l; LC<sub>50</sub> 96 hr (Bluegill sunfish): 5.8 mg/l; LC<sub>50</sub> 96 hr (Rainbow

trout): 2.8 mg/l; LC<sub>50</sub> 96 hr (Rainbow trout): 1.2 mg/l; LC<sub>100</sub> 96 hr (Rainbow trout): 4.95 mg/l; EC<sub>50</sub> 48 hr (Daphnia magna): 4.0 mg/l; EC<sub>50</sub> 48 hr (Daphnia magna): 1.0 mg/l; EC<sub>100</sub> 48 hr (Daphnia magna): 10.0 mg/l.

*Exposure.* Processing: Dermal, up to 2 hrs/da, up to 100 da/yr.

*Environmental Release/Disposal.* No release to air, water and land. Disposal by incineration.

#### P85-813

*Importer.* Marubeni America Corporation.

*Chemical.* (G) Copolymer of unsaturated polyester and allyl compounds.

*Use/Import.* (S) Coating for woodwork. Import range: 30,000-120,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* No data submitted.

*Environmental Release/Disposal.* No data submitted. Disposal by incineration.

#### P85-814

*Importer.* Marubeni America Corporation.

*Chemical.* (G) Copolymer of unsaturated polyester and allyl compounds.

*Use/Import.* (S) Coating for woodwork. Import range: 30,000-120,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* No data submitted.

*Environmental Release/Disposal.* No data submitted. Disposal by incineration.

#### P85-815

*Importer.* Marubeni America Corporation.

*Chemical.* (G) Copolymer of unsaturated polyester and allyl compounds.

*Use/Import.* (S) Coating for woodwork. Import range 30,000-120,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* No data submitted.

*Environmental Release/Disposal.* No data submitted. Disposal by incineration.

#### P85-816

*Importer.* Marubeni America Corporation.

*Chemical.* (G) Copolymer of unsaturated polyester and allyl compounds.

*Use/Import.* (S) Putty for vehicle. Import range: 20,000-80,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* No data submitted.

*Environmental Release/Disposal.* No data submitted. Disposal by incineration.

#### P85-817

*Importer.* Marubeni America Corporation.

*Chemical.* (G) Copolymer of unsaturated polyester and allyl compounds.

*Use/Import.* (S) Putty for vehicle. Import range: 20,000-80,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* No data submitted.

*Environmental Release/Disposal.* No data submitted. Disposal by incineration.

#### P85-818

*Importer.* Confidential.

*Chemical.* (G) Benzenesulfonic acid, 4-[[4-substituted]-3-methyl-5-oxo-2-pyrazolin-1-yl]-, salt

*Use/Import.* (G) Open, non-dispersive use. Import range 1,500-5,000 kg/yr.

*Toxicity Data.* No data on the PMN substance submitted.

*Exposure.* Import and processing: dermal and inhalation, a total of 5 workers, up to 2 hrs/wk at 400 man hours/yr.

*Environmental Release/Disposal.* No data submitted.

#### P85-819

*Manufacturer.* Resinall Corporation.

*Chemical.* (G) Tall oil fractions, unsaturated hydrocarbon resin, dieneophile modified polymer with pentaerythritol.

*Use/Production.* (G) Resin binder for printing inks. Prod. range: confidential.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture: Dermal, a total of 7 workers, up to 6 hrs/da, up to 300 da/yr.

*Environmental Release/Disposal.* 50 lbs released to air, with 5 to 50 lbs to land. Disposal by sanitary landfill.

#### P85-820

*Manufacturer.* Resinall Corporation.

*Chemical.* (G) Carboxylic modified rosin.

*Use/Production.* (S) Industrial processing aid in rubber compounding, pigment resination and tackifier for adhesives. Prod. range: 100,000-300,000 kg/yr.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture: Dermal, a total of 5 workers, up to 6 hrs/da, up to 20 da/yr.

*Environmental Release/Disposal.* 180 kg/batch released to air with 20 to 180 kg/batch land.



Dated: April 19, 1985.

Linda A. Travers,

Acting Director, Information Management Division.

[FR Doc. 85-10151 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59712; FRL-2826-1]

### Certain Chemicals; Premanufacture Notices

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of the final rule published in the Federal Register of May 13, 1983 (48 FR 21722). In the Federal Register of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. PMNs for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of three such PMNs and provides a summary of each.

**DATES:** Close of Review Period:

Y 85-55—May 2, 1985.

Y 85-56, Y 85-57—May 6, 1985.

### FOR FURTHER INFORMATION CONTACT:

Wendy Cleland-Hamnett, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street SW., Washington, DC 20460 (202-382-3725).

**SUPPLEMENTARY INFORMATION:** The following notice contains information extracted from the non-confidential version of the submission by the manufacturer on the exemption received by EPA. The complete non-confidential document is available in the Public Reading Room E-107 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

Y 85-55

**Manufacturer:** Confidential.

**Chemical:** (G) Polyoxymethylene ester modified alkoxysilane.

**Use/Production:** (S) Component of products for use as dispersing agents in coating formulations. Prod. range: Confidential.

**Toxicity Data:** No data on the PMN substance submitted.

**Exposure:** Manufacture: Dermal, a total of 1 worker, up to 6 hrs/da, up to 33 da/yr.

**Environmental Release/Disposal:** Confidential.

Y 85-56

**Manufacturer:** Spencer Kellogg Division of Textron Inc.

**Chemical:** (G) Alkyd resin.

**Use/Production:** (G) An alkyd resin to be used in an open, non-dispersive use. Prod. range: Confidential.

**Toxicity Data:** No data submitted.

**Exposure:** Confidential.

**Environmental Release/Disposal:** No data submitted.

Y 85-57

**Importer:** Confidential.

**Chemical:** (G) 1-substituted propane, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, monosodium salt, polymer with 2-propenamide and 2 propenoic acid, sodium salt.

**Use/Import:** Confidential.

**Toxicity data:** No data submitted.

**Exposure:** No data submitted.

**Environmental Release/Disposal:** No data submitted.

Dated: April 22, 1985.

V. Paul Fuschini,

Acting Director, Information Management Division.

[FR Doc. 85-10149 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

[PF-409; PH-FRL 2826-5]

### Certain Companies; Pesticide Tolerance Petitions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has received pesticide petitions relating to the establishment, amendment, and/or correction of tolerances for certain pesticide chemicals in or on certain agricultural commodities.

**ADDRESS:** By mail, submit comments identified by the document control number [PF-409] and the petition number, attention Product Manager (PM) named in each petition, at the following address:

Information Services Section (TS-757C), Program Management and Support Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring comments to:

Information Services Section (TS-757C), Environmental Protection

Agency, Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed in response to this notice will be available for public inspection in the Information Services Section office at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

### FOR FURTHER INFORMATION CONTACT:

By mail: Registration division (TS-767C),

Attn: (Product Manager (PM) named in each petition), Environmental Protection Agency, Office of Pesticide Programs, 401 M St., SW., Washington, D.C. 20460.

In person: Contact the PM named in each petition at the following office location/telephone number:

Product manager	Office location/ telephone number	Address
PM-12, Jay Ellenberger.	Rm. 202, CM#2 (703-557-2386).	EPA, 1921 Jefferson Davis Hwy., Arlington, VA 22202
PM-17, Timothy A. Gardner.	Rm. 207, CM#2 (703-557-2690).	Do.

**SUPPLEMENTARY INFORMATION:** EPA has received pesticide petitions (PP) relating to the establishment, amendment, and/or correction of tolerances for certain pesticide chemicals in or on certain agricultural commodities.

### I. Initial Filing

PP 5F3208. Union Carbide Agricultural Products Co., Inc., P.O. Box 12014, Research Triangle Park, NC 27709. Proposes amending 40 CFR 180.169 by establishing a tolerance for residues of the insecticide carbaryl (1-naphthyl N-methylcarbamate) in or on the commodity pineapples at 2.0 parts per million (ppm). The proposed analytical method for determining residues in high pressure liquid chromatography using fluorescent detection. PM-12

### II. Amended Petition

PP 2F2657. Shell Oil Co., 1025 Connecticut Ave., NW., Washington, D.C. 20036. EPA issued a notice,



published in the **Federal Register** of February 8, 1984 (49 FR 4841), which announced that Shell Oil Co. had submitted PP 2F2657 to the Agency proposing to amend 40 CFR 180.379 by establishing tolerances for residues of the insecticide cyano (3-phenoxyphenyl)methyl-4-chloro- $\alpha$ -(1-methylethyl) benzeneacetate in or on certain commodities.

Shell Oil Co. has amended the petition by adding the commodity raisins at 30 ppm. The proposed analytical method for determining residues is gas chromatography. (PM-17)

### III. Pesticide Petition; Correction

EPA issued a notice, published in the **Federal Register** of March 6, 1985 (50 FR 9122), which announced that Mobay Chemical Corp., P.O. Box 4913, Hawthorne Road, Kansas City, MO 64120, proposes amending 40 CFR Part 180 by establishing tolerances for the residues of the insecticide [Z]- $\alpha$ -(diethoxyphosphinothioyl)oxyimino]benzeneacetone nitrile and its cholinesterase-inhibiting metabolites in or on the agricultural commodity corn, sweet (kernels plus cobs with husk removed) at 0.05 ppm.

In the FR Doc. 85-4992, appearing at page 9123, in the first column, the pesticide petition (PP) number in item 2 under Initial Filings was inadvertently filed a "PP 5E3187", and is corrected to read "PP 5E3205". (PM-12)

(Sec. 408(d)(2) 68 Stat. 512, [21 U.S.C. 346a(d)(2)])

Dated: April 19, 1985.

Robert V. Brown,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 85-10144 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

### [OPTS-51529B; FRL-2826-2]

#### Certain Chemicals; Premanufacture Notice; Termination of Review Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is revoking effective April 20, 1985, immediately following the signing of a Consent Order for the new chemical substance subject to premanufacture notice (PMN) P84-968, the remaining portion of a 90-day extension of the review period for PMN P84-968, under the authority of section 5(c) of the Toxic Substances Control Act (TSCA).

**FOR FURTHER INFORMATION CONTACT:** Anna Coutlakis, Chemical Control Division (TS-794), Environmental

Protection Agency, Rm. E-613-B, 401 M St., SW., Washington, D.C. 20460, (202) 382-2252.

**SUPPLEMENTARY INFORMATION:** The original 90-day review period for PMN P84-968 was scheduled to expire on October 14, 1984. EPA published a section 5(c) extension notice for the PMN in the **Federal Register** of October 19, 1984 (49 FR 41101) to provide the Agency with sufficient time to issue an order under section 5(e). The Order would have prohibited the Company from manufacturing the PMN substance in, or importing it into, the United States pending the submission and evaluation of test data addressing the potential risk of injury to human health. After the Order was proposed, the Company suspended the notice review period and submitted more data and information. In light of this new data and information, EPA concluded that, if the Company were willing to enter into an appropriate Consent Order, the risks from the PMN substance would be reduced to acceptable levels. The Company agreed to such an approach. The review period, including the extension under section 5(c), would have expired May 18, 1985. The Consent Order was signed April 19, 1985 and goes into effect April 20, 1985. Therefore, EPA is revoking the remaining portion of the extended review period effective April 20, 1985.

Dated: April 18, 1985.

Edwin F. Tinsworth,

Acting Director, Office of Toxic Substances.

[FR Doc. 85-10148 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

### [SAB-FRL-2825-3]

#### Science Advisory Board Clean Air Scientific Advisory Committee; Open Meeting

Under Pub. L. 92-463, notice is hereby given of a meeting of the Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board. The meeting will be held May 13-15, 1985, starting at 9:00 am on May 13 and ending at approximately noon on May 15. The meeting will be held at the Rosslyn Westpark Hotel, 1900 North Fort Myer Drive, Arlington, Virginia.

The purpose of the meeting is to allow the Committee to review and provide its advice to the Agency on: (1) The August 1984 external review draft of the EPA's revised *Air Quality Criteria Document for Lead*; and (2) the EPA's first draft of the *Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information Draft Staff Paper*. The purpose of the staff paper is to evaluate and interpret

the most relevant scientific and technical information reviewed in the criteria document in order to better specify the critical elements which the EPA staff believes should be considered in the possible revision of the primary and secondary National Ambient Air Quality Standards for lead. This assessment is intended to help bridge the gap between the scientific review contained in the criteria document and the judgments required of the Administrator in setting ambient standards for lead.

Copies of the August 1984 draft criteria document may be obtained by writing or calling the Office of Research and Development Publications Center, CERL-FRN, U.S. EPA, 21 West St. Clair Street, Cincinnati, Ohio, 45268 (513) 684-7562. Please ask for EPA document 600/8-83-028B, Vols. I-IV, August 1984. Copies of the draft staff paper may be obtained from Jeff Cohen, Strategies and Standards Division, Office of Air Quality Planning Standards (MD-12), U.S. EPA, Research Triangle Park, North Carolina, 27711, (CML) (919) 541-5531, (FTS) 629-5531. Written comments on the draft staff paper will be accepted through the 15th of July. Comments should be sent to Jeff Cohen at the previous address.

The meeting is open to the public. Any member of the public wishing to attend or obtain information should contact Mr. Robert Flaak, Executive Secretary, Clean Air Scientific Advisory Committee (CASAC), Science Advisory Board (A-101-F), U.S. EPA, Washington, DC, 20460 (202) 382-2552, prior to the meeting. Persons wishing to make statements at the meeting must contact Mr. Flaak no later than close of business on May 7, 1985.

Terry F. Yosie,

Director, Science Advisory Board.

April 15, 1985.

[FR Doc. 85-10146 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

### [ER-FRL-2826-4]

#### Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared April 8, 1985 through April 12, 1985 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at



(202) 382-5075/76. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated October 19, 1984 (49 FR 41108).

#### Draft EISs

ERP No. D-AFS-C65001-PR, Rating EC2, Caribbean Nat'l Forest and Luquillo Experimental Forest, Land and Resource Mgmt. Plan, Puerto Rico. **SUMMARY:** EPA expressed its concern that the DEIS did not adequately analyze potential long-term soil erosion impacts and water quality issues associated with timber harvesting activities. Overall, EPA agreed that the selected alternative represents a balance of the forests uses and resources. However, EPA believes the FEIS should include appropriate mitigating measures for potential long-term impacts to water quality and soil resources.

ERP No. D-AFS-D85012-00, Rating EC2, Jefferson Nat'l Forest Land and Resource Mgmt. Plan, WV, VA, and KY. **SUMMARY:** EPA's review suggests that the combined effects of proposed timbering and mineral extraction may result in significant cumulative impacts for which mitigation is not provided. Further, EPA believes that increased emphasis must be given to water quality issues and its more dependent ecosystem in order to assure that existing water quality and ecosystems are not significantly impacted. Finally, EPA believes that the proposed plan should incorporate a more comprehensive watershed management scheme than is identified.

ERP No. DS-COE-E32026-AL, Rating EO2, Mobile Harbor Channel Improvements, Construction and Maintenance, Offshore Dredged Material Disposal Site, Designation, AL. **SUMMARY:** EPA believes even though the current proposal has been downsized from the original onshore design, its impact remains geographic in scope, severe and irreversible. While EPA endorses the ocean disposal concept, we have significant environmental objections to utilizing a portion of the dredged material to create a 1000 acre island in Mobile Bay to function as an island terminal facility. EPA feels that practical and more environmentally sensitive alternatives exist for both dredged material disposal and port related developments and would like to continue discussions on this issue.

ERP No. DS-FHW-H40133-1A, Rating EC2, IA-58 and US 218 (formerly 518) Relocation and Improvement, Relocated US 20 in Cedar Falls to IA-3 in Waverly, IA. **SUMMARY:** EPA requested that the noise section be expanded to include

information on the number and location of sites adversely impacted by noise.

ERP No. DS-FRC-L05018-AK, Rating EC2, Bradley Lake Hydroelectric Project, Construction and Operation, Permit, AK. **SUMMARY:** EPA suggested that the FSEIS place greater emphasis on summarizing the many volumes of supporting documents associated with the project. Also, expansion of the access alternatives evaluation was requested. Finally, EPA requested the opportunity to review monitoring plans and reports pertinent to a variety of project impacts and mitigation measures.

ERP No. RD-NOA-B91021-MA, Rating LO, Northeast Multi-Species Fishery Mgmt. Plan, Adoption, Approval, MA, ME, NH, RI, and CT. **SUMMARY:** EPA believes, from its areas of jurisdiction and expertise, that the fishery management plan will not cause significant adverse impacts on the environment.

ERP No. D-SCS-E36152-MS, Rating LO, Tallahaga Creek Watershed Flood Protection Plan, MS. **SUMMARY:** EPA does not have any significant and or long-term environmental objections to the current proposal and believes that sufficient information is provided in the DEIS.

ERP No. D-UMT-K54015-CA, Rating LO, San Diego East Urban Corridor Transportation Improvement, CA. **SUMMARY:** EPA has not identified any potential environmental impacts requiring substantive changes to the proposal.

#### FINAL EISs

ERP No. F-COE-D36082-VA, Roanoke R. Upper Basin Flood Damage Reduction, Headwaters Area, VA. **SUMMARY:** EPA reviewed the FEIS and found no objections to the project's implementation. The COE had addressed and incorporated each of EPA's requested modifications as noted in the DEIS.

ERP No. F-COE-G39012-LA, Louisiana Coastal Area, Freshwater Diversion to Barataria and Breton Sound Basins, LA. **SUMMARY:** The FEIS adequately responds to EPA's comments issued on the DEIS and EPA did not identify any new concerns with regard to the proposed action.

ERP No. F-FHW-F40195-MN, TH-55/Hiawatha Ave. Reconstruction, 59th St. to Franklin Ave., and CSAH 62 (Crosstown Highway) Extension, TH-55 to 46th Ave. South, MN. **SUMMARY:** EPA's review of the FEIS did not identify any significant environmental impacts requiring changes to the proposed project.

ERP No. F-USN-K40148-CA, Port Chicago Hwy., Main St. and Waterfront

Rd., Explosive Safety Closure, Naval Weapons Station, CA. **SUMMARY:** EPA had no comments on the FEIS.

#### Amended Notices

The following review was completed during the week of February 25, through March 1, 1985 and should have appeared in the FR Notice published on March 15 March 15, 1985.

ERP No. F-BLM-K03012-00, Celeron/All American and Getty Crude Oil Pipeline Project, Construction and Operation, Right-of-Way Permits, Emidio Station, CA. **SUMMARY:** The FEIS adequately responds to most of the environmental concerns raised in EPA's review of the DEIS. However, EPA continues to have environmental concerns with the action taken to initiate the construction of the McCameys to Freeport Extension and believes that the FEIS is deficient in providing information to assess related environmental impacts of the extension. The EIS does not address the impacts and related mitigation requirements with respect to the Edwards aquifer. ERP suggested that a supplement to the EIS would be required to satisfy the NEPA requirements associated with the McCamey to Freeport Extension. The following review was published in the April 12, 1985 FR Notice and with the incorrect summary paragraph. The correct summary of the EPA comments is below.

ERP No. F-OSM-L67014-WA, John Henry No. 1 Mine Operation, Permit, WA. **SUMMARY:** EPA suggested several stipulations for inclusion in the Record of Decision for the FEIS, and conditions on the Office of Surface Mining permit, if approved. The stipulations and conditions were suggested in order to more formally define the monitoring program, and to establish a firm commitment from the project sponsor for their proposed reclamation plan.

Dated: April 23, 1985.

Allan Hirsch,

Director, Office of Federal Activities,

[FR Doc. 85-10196 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-2826-3]

#### Environmental Impact Statements; Availability

##### Responsible Agency

Office of Federal Activities, General Information (202) 382-5073 or (202) 382-5075.

Availability of Environmental Impact Statements filed April 15, 1985 Through April 19, 1985 Pursuant to 40 CFR 1506.9.



EIS No. 850153, Draft, FAA, CA, Fremont General Aviation Reliever Airport Development, Alameda and Fremont Counties, Due: June 24, 1985, Contact: Martin Convisser (202) 426-4357.

EIS No. 850154, Final, FHWA, TX, Farm to Market Highway 734/Parmer Lane Highway Extension, Construction, Farm to Market Highway 1325 to Ranch to Market Highway 620 Travis and Williamson Counties, Due: May 28, 1985, Contact: W. L. Hall (512) 482-5966, Hall (512) 482-5966.

EIS No. 850155, Draft, EPA, FL, North Pinella County Wastewater Management Facilities Development, Grant, North Pinella County, Due: June 25, 1985, Contact: Ronald Mikulak (404) 881-3776.

EIS No. 850156, Final, ADOPTION, CGD, WA, Duwamish River Construction Bridges, Construction, Permit, King County, Due: May 28, 1985, Contact: Wayne Lee (206) 442-5864.

EIS No. 850157, Draft, BLM, UT, Box Elder Planning Area, Resource Management Plan, Box Elder County, Due: July 25, 1985, Contact: Dennis Oaks (801) 524-6767.

EIS No. 850158, Final, COE, MS, LA, Lake Pontchartrain Basin and Mississippi Sound Freshwater Diversion, Mississippi and Louisiana Estuarine Areas, Due: May 28, 1985, Contact: Dennis Chew (503) 838-2523.

EIS No. 850159, Final, USAF, NM, Melrose Air Force Bombing Range Expansion, Curry and Roosevelt Counties, Due: May 28, 1985, Contact: Roy Barker (804) 764-4430.

EIS No. 850160, Final, COE, CA, Oakland Inner Harbor Deep Draft Navigation Improvements, Alameda County, Due: May 28, 1985, Contact: Les Tong (415) 974-0439.

EIS No. 850161, Final, COE, OK, Arkansas City, Flood Control Plan, Arkansas and Walnut Rivers, Cowley County, Due: May 28, 1985, Contact: Buell Atkins (918) 581-7857.

EIS No. 850162, DRevised, COE, KS, Great Bend, Kansas Local Protection Plan, Construction, Barton County, Due: June 10, 1985, Contact: Buell Atkins (918) 581-7857.

EIS No. 850163, Draft, SCS, MO, Big Creek-Hurricane Creek Watershed Protection and Flood Prevention Plan, Livingston and Carroll Counties, Due: June 10, 1985, Contact: Paul Lawson (314) 875-5214.

EIS No. 850164, Final, BLM, CO) Northeast Resource Area, Resource Management Plan, Due: May 28, 1985, Contact: Frank Young (303) 236-4399.

#### Amended notices:

EIS No. 850165, Draft, AFS, MT, Hyalite-Porcupine Buffalo Horn WSA's

Designation and Management, Gallatin National Forest, Gallatin and Park Counties, Due: July 15, 1985, Contact: Robert Breazeale (406) 587-6700, Should have appeared in 4-5-85 FR.FR.

EIS No. 850088, Draft, BLM, BIA, NM, Jackpile-Paguate Uranium Mine Reclamation Plan, Approval, Cibola County, Due: October 10, 1985, Published FR 3-29-85—Review extended.

Dated: April 23, 1985.

Allan Hirsch,

Director, Office of Federal Activities.

[FR Doc. 85-10197 Filed 4-25-85; 8:45 am]

BILLING CODE 5560-50-M

[ER-FRL-2826-5]

#### Intent To Prepare an Environmental Impact Statement

Responsible Office: U.S. Environmental Protection Agency Region III, Philadelphia, Pennsylvania. Purpose: In accordance with section 511(c) of the Clean Water Act and section 102(2)(c) of the National Environmental Policy Act, EPA is notifying government agencies and the public that an EIS will be prepared to address wastewater management in the West Rehoboth Sanitary Sewer District, Sussex County, Delaware.

**FOR FURTHER INFORMATION CONTACT:** Mr Richard V. Pepino Environmental Impact and Marine Policy Branch U.S. Environmental Protection Agency Region III 841 Chestnut Building Philadelphia, Pennsylvania 19107 Phone No. (215) 597-9301.

#### Summary

##### 1. Description of Proposed Action

The Environmental Protection Agency will prepare an Environmental Impact Statement (EIS) in conjunction with the planning of wastewater treatment needs for the West Rehoboth Sanitary Sewer District, Sussex County, Delaware. This action is in accordance with requirements of the National Environmental Policy Act, the Clean Water Act Amendments, and related EPA regulations.

##### 2. Significant Issues

The EIS will consider the impacts of implementing alternative wastewater treatment strategies developed through the planning process. The major issues to be evaluated include increased development pressure, impacts on prime agricultural land and environmentally sensitive areas, water quality impacts, and feasibility of alternative technologies.

#### 3. Public Participation Program

If you or your organization would like additional information, wish to submit information to EPA, or wish to be placed on the project mailing list please contact Richard V. Pepino of the Environmental Impact and Marine Policy branch at the above address.

Dated: April 23, 1985.

Allan Hirsch,

Director Office of Federal Activities.

[FR Doc. 85-10195 Filed 4-25-85; 8:45 am]

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[OW-FRL-2825-2]

#### State of Michigan National Pollutant Discharge Elimination System (NPDES) Pretreatment Program Reapproval

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** On April 16, 1985, the Environmental Protection Agency (EPA) reapproved the State of Michigan's NPDES State pretreatment program. This action reauthorizes the State of Michigan to administer the National pretreatment program as it applies to municipalities and industries within the State.

**ADDRESS:** The documents that form the basis for EPA's reapproval of the Michigan NPDES State pretreatment program are located at the EPA Region V Office, 230 South Dearborn Street, Chicago, Illinois, 60604. Please contact John J. O'Grady, Water Quality Permits Section (5WQP), (312) 353-2105.

**FOR FURTHER INFORMATION CONTACT:** John J. O'Grady, Water Quality Permits Section (5WQP), U.S. Environmental Protection Agency, Region V Office, 230 South Dearborn Street, Chicago, Illinois, 60604, (312) 353-2105.

#### SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Court Order.
- III. Responsiveness Summary (Pursuant to 40 CFR 123.61(b)).
  - A. Summary of Significant Activities.
  - B. Response to Comments Submitted.
    1. Review, Analysis, and Response to NWF's Original Comments.
      - a. Integration of Toxic Chemical Evaluation Section.
      - b. Qualifications of Other MDNR Pretreatment Staff.
      - c. MDNR Environmental Protection Bureau Reorganization.
    2. Review, Analysis, and Response to NWF's Comments, Dated February 8, 1985, on the Reconsideration of EPA's



#### Approval of Michigan's Pretreatment Program.

- a. Michigan's Revised Pretreatment Rules.
- b. "Quality Control" of Pretreatment.
  1. Local Limits.
  2. Legal Authority Reviews.
- c. Modifying POTWs' NPDES Permits to Incorporate Pretreatment Conditions.
3. Summary and Conclusion.

#### IV. Federal Register Notice of Approval of State NPDES Programs or Modifications.

#### V. Review Under Executive Order 12291 and the Regulatory Flexibility Act.

#### I. Background

On June 26, 1978, EPA promulgated the General Pretreatment Regulations (40 CFR Part 403). Amendments to the General Pretreatment Regulations were promulgated on January 28, 1981 (46 FR 9404). These regulations, mandated by the Clean Water Act of 1977 (Pub. L. 95-217), govern the control of industrial wastes introduced into Publicly Owned Treatment Works (POTWs), commonly referred to as municipal sewage treatment plants. The objectives of the regulations are to: (1) Prevent the introduction of pollutants into POTWs which will interfere with the operation of a POTW, including interference with its use or disposal of municipal sludge; (2) prevent the introduction of pollutants into POTWs which will pass through the treatment works or otherwise be incompatible with such works; and (3) improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludges.

The guidelines and regulations which EPA has promulgated at 40 CFR Part 123, under the authority of sections 304(i)(2) and 402(b) of the Clean Water Act, apply to all aspects of state NPDES programs, including NPDES state pretreatment program applications. In addition, EPA has promulgated regulations at 40 CFR 403.10 that are particularly applicable to NPDES state pretreatment program applications. These regulations, among other things, require each state applicant to provide a description of the funding and personnel available to implement the program and demonstrate that the funding and qualified personnel are sufficient to carry out the program (40 CFR 403.10 (f)(3) & (g)(2)).

On October 28, 1982, Michigan submitted an application to EPA to add the pretreatment program to its approved NPDES program. On December 3, 1982, EPA published a notice in the Federal Register seeking comment on Michigan's application (47 FR 54477). One of the commentators on Michigan's application was the National Wildlife Federation (NWF). NWF stated that in light of the December 20, 1982,

internal reorganization within the Michigan Department of Natural Resources (MDNR), the State agency which administers the NPDES and pretreatment program in Michigan, clarification of the resulting administrative responsibilities for the Michigan pretreatment program was needed.

In response, on January 28, 1983, representatives from EPA Region V and the State of Michigan met with NWF and other environmental groups to listen to their concerns, and to explain why MDNR had been reorganized and how the reorganization would strengthen the pretreatment program. MDNR detailed the number of personnel from various MDNR offices to be committed to the pretreatment program and explained the pretreatment role to be played by experts from MDNR's Toxic Chemical Evaluation Section (TCES) in the regulation of toxic pollutants. The State agreed to provide NWF with a written description of pretreatment personnel responsibilities.

On February 10, 1983, Charles H. Sutfin, Water Division Director for EPA Region V, informed NWF that after considering the comments made by NWF and others, EPA Regional staff had decided to recommend that the EPA Administrator approve the Michigan pretreatment program.

On February 18, 1983, NWF wrote to EPA to express continued concern whether MDNR was committing sufficient staff expertise to the pretreatment program and requesting written documentation of internal Michigan task assignments. EPA mailed this information to NWF on April 4, 1983. On April 26, 1983, NWF wrote to EPA to again express their concern that Michigan had not yet demonstrated that qualified personnel were available to implement the pretreatment program. NWF argued that the task assignments document, transmitted to them on April 4, did not demonstrate the necessary academic credentials or relevant experience of personnel assigned to the program and did not formally assign TCES personnel into the pretreatment process.

On June 7, 1983, EPA approved Michigan's NPDES State pretreatment program (48 FR 27291, June 14, 1983). This action authorized the State of Michigan to administer the National pretreatment program as it applies to municipalities and industries within the State. On September 5, 1983, NWF and the Michigan United Conservation Clubs (MUCC) filed a petition with the U.S. Court of Appeals for the Sixth Circuit (Case No. 83-3616) for review of EPA's approval, under the Clean Water Act, of

Michigan's application to administer the NPDES pretreatment program. In response, EPA filed a motion on May 16, 1984, requesting that the Sixth Circuit remand the approval to EPA for reconsideration, without requiring withdrawal of the program prior to that reconsideration. In its brief, EPA acknowledged that it had not adequately procedurally documented the factual premises and reasons supporting its approval of Michigan's application. EPA moved the Sixth Circuit Court for an order: (1) Remanding for reconsideration EPA's approval of the State of Michigan's NPDES State pretreatment program; (2) allowing Michigan's approved NPDES State pretreatment program to continue in effect pending final action on its reconsideration; and (3) staying further proceedings pending final action on its reconsideration.

#### II. Court Order

The U.S. Court of Appeals for the Sixth Circuit granted EPA's motion on September 27, 1984. The Sixth Circuit Court, at EPA's request, allowed Michigan's NPDES State pretreatment program to continue in effect pending final action on EPA's reconsideration. The Sixth Circuit Court did not rule on the substantive validity of the Michigan NPDES State pretreatment program. The lawsuit was stayed pending the reconsideration. The Court Order required EPA to take final action upon Michigan's NPDES State pretreatment program within 180 days of entry of the Court Order (by March 26, 1985\*), including a detailed written statement of the basis for its decision and a response to all comments submitted. The Court Order also required EPA to take the following interim steps:

1. EPA was to file monthly reports with the Sixth Circuit Court, beginning October 27, 1984, describing the status of its reconsideration of the Michigan NPDES State pretreatment program application. Monthly reports have been filed with the Sixth Circuit Court on October 24, 1984; November 27, 1984; January 2, 1985; January 24, 1985; March 1, 1985; and March 26, 1985.

2. EPA was to publish a Federal Register notice soliciting additional comments on the approval of Michigan's NPDES State pretreatment program application. The public notice appeared in the Federal Register on December 27, 1984 (49 FR 50199 et seq.).

3. EPA was to hold a public hearing on the Michigan NPDES State pretreatment program application. The public hearing was conducted in January 29, 1985.



4. EPA was to make a new final decision, accompanied by a detailed written statement of the basis for its decision and a response to all comments submitted. EPA was to take final action upon Michigan's pretreatment program application within 180 calendar days of the date of the Court Order (March 26, 1985\*).

\*NB: This date has been extended for 40 days until May 5, 1985.

### III. Responsiveness Summary (Pursuant to 40 CFR 123.61(b))

#### A. Summary of Significant Activities

MDNR drafted proposed amendments to the Michigan Water Resources Commission (WRC) Part 21 Rules: *Wastewater Discharge Permits—Pretreatment Program*, which were approved by the WRC for public notice on June 21, 1984. EPA provided comments dated June 29, 1984, on the rules. MDNR subsequently published a notice soliciting additional comments on both the proposed pretreatment rules and the EPA comments, and informed the public of hearings to be held on the public notice package. Public hearings were held in Lansing, Michigan on August 13, 1984, and in Houghton, Michigan on August 15, 1984. On August 28, 1984, the public hearing record closed, with written statements postmarked by August 24, 1984, being introduced into the hearing record.

Subsequent to the public hearings and notice period, and based upon the EPA comments, MDNR made additional revisions to the rules and mailed them to EPA on October 26, 1984, as well as to WRC members, and interested industrial user and environmental groups for further review. On November 15, 1984, revisions to the administrative rules for the pretreatment program were approved by the WRC. The rules had received the support of the Michigan Water Pollution Control Federation, the Michigan Clean Water Coalition, the Ford Motor Company, the National Council of the Paper Industry for Air and Stream Improvements, Inc. (NCASI), NWF, and MUCC.

On November 19, 1984, EPA received MDNR's NPDES State pretreatment program application amendments, dated November 16, 1984, that included the proposed pretreatment rules, a revised narrative, and attachments to the program narrative on funding sources, organizational changes, position descriptions, and personnel qualifications. The revised program narrative addressed changes in the staffing and organization, the addition of a pretreatment program coordinator, utilization of available expertise within

MDNR for toxicant evaluation, financial resources, and legal review of ordinances.

On December 17, 1984, Valdas V. Adamkus, Regional Administrator for EPA Region V, transmitted a letter to Ronald O. Skoog, Director of MDNR, informing MDNR of the public notice in the *Federal Register* on the reconsideration of EPA's approval of the Michigan pretreatment program, and of the public hearing to be held on January 29, 1985, in Lansing, Michigan. On December 27, 1984, the public notice appeared in the *Federal Register* (49 FR 50199 et seq.), soliciting additional comments on Michigan's pretreatment program and announcing the public hearing scheduled for January 29, 1985; that document was characterized as a Proposed Rule, but should have been classified as a Notice.

On January 3, 1985, a workload analysis was performed by the EPA Region V Office on the Michigan pretreatment program that concluded that MDNR had sufficient staff to operate the pretreatment program in Michigan.

On January 7, 1985, MDNR submitted a revised pretreatment program narrative, dated January 4, 1985, to EPA.

On January 11, 1985, the Michigan Legislative Service Bureau certified the proposed pretreatment rules' format. On January 18, 1985, the Michigan Attorney General certified the proposed pretreatment rules' legality.

On January 29, 1985, the public hearing for the reconsideration of the Michigan pretreatment program was held at the Law Building Auditorium in Lansing, Michigan. EPA formally requested additional comments on Michigan's NPDES State pretreatment program, and MDNR's ability to effectively administer this program consistent with Federal and State requirements. Thirty individuals were in attendance representing industries, municipalities, environmental groups, MDNR, and the EPA Region V Office.

Only two statements were presented before the hearing panel. Paul D. Zugger, Executive Secretary of the WRC, and Chief of MDNR's Surface Water Quality Division (SWGD), presented a statement reaffirming Michigan's commitment to the pretreatment program, and urging EPA to reapprove Michigan's pretreatment program. He also stressed that MDNR desired to be treated on an equal basis with other States in the Region, and not preferentially treated as a result of the Court Order. Mark Van Putten, on behalf of NWF and MUCC, presented a statement that noted significant positive changes in MDNR's program, and that praised Mr. Zugger for

effectively turning the Michigan pretreatment program around, under the auspices of the EPA Region V Office.

He commented that NWF and MUCC were generally pleased with the significant progress that had occurred in the program. He urged EPA to continue to assist MDNR in the development of its pretreatment program, and for EPA to continue in its overview role of that program.

The public comment period closed on February 9, 1985. The only comments received by the EPA Region V Office, were from Mark Van Putten, on behalf of NWF and MUCC. His comments were dated February 8, 1985, and were received via Express Mail on February 11, 1985.

On March 13, 1985, the proposed pretreatment rules package was approved by the Michigan Joint Legislative Rules Committee. On March 21, 1985, the WRC approved the proposed pretreatment rules. On March 22, 1985, the rules were transmitted to the Office of the Governor of Michigan. On March 26, 1985, the proposed pretreatment rules were filed with the Office of the Secretary of State and with the *Michigan Register*. On April 11, 1985, the proposed amendments to the WRC Part 21 Rules: *Wastewater Discharge Permits—Pretreatment Program* became effective.

#### B. Response to Comments Submitted

In response to the public notice in the *Federal Register* (49 FR 50199 et seq., December 27, 1984) soliciting additional comments on the reconsideration of EPA's approval of the Michigan pretreatment program, EPA received only one set of comments. The comments were from Mark Van Putten on behalf of NWF and MUCC, dated February 8, 1985, and were received at the EPA Region V Office on February 11, 1985.

The combined comments of NWF and MUCC, will be referred to as, "NWF's comment(s)".

#### 1. Review, Analysis, and Response to NWF's Original Comments

This review, analysis, and response is based upon the NWF comments which were expressed in the following correspondence:

- Letter to Robert R. Robichaud from Mark Van Putten, dated December 30, 1982;
- Letter to Charles H. Sutfin from Mark Van Putten, dated April 26, 1983;
- Letter to Charles H. Sutfin from Mark Van Putten, dated September 2, 1983;



• Petition to the U.S. Court of Appeals for the Sixth Circuit from Mark Van Putten, dated September 5, 1983; and

• Pre-argument statement to the U.S. Court of Appeals for the Sixth Circuit from Mark Van Putten, dated September 16, 1983.

a. *Integration of Toxic Chemical Evaluation Section (TCES) Staff*—(1) *NWF's Comments:* (a) There was no formal integration of MDNR's staff with demonstrated credentials in toxicants control, into the implementation and administration of the pretreatment program.

(b) The assignment of only 1.5 full-time equivalents (FTEs) from the TCES staff to the pretreatment program, effectively isolated the MDNR staff with the demonstrated credentials for toxicant evaluation from the program. TCES's organizational role was vague, ad hoc, and advisory.

(2) *NWF's Rationale:* NWF's comments stemmed from three basis areas of concern.

(a) First, NWF felt that the reorganization of MDNR's Environmental Protection Bureau (which was effective on December 20, 1982, and which had occurred after MDNR had submitted its formal application for pretreatment program approval) had left the Michigan application vague in regard to the integration of the TCES staff into the pretreatment program, and therefore, deficient (in NWF's opinion) in terms of 40 CFR 403.10 ((f)(2) and (g)(1)(iii)) requirements.

(b) Second, NWF was looking for a formal, structured role for the TCES experts in the following areas:

- Identifying and categorizing industrial users;
  - Reviewing reports for and making determinations on fundamentally different factors (FDF) variance requests;
  - Monitoring compliance and deciding upon appropriate compliance follow-up activities;
  - Providing technical assistance to POTWs in program development and implementation; and
  - Reviewing POTW program submissions and requests for authorization to revise categorical pretreatment standards to reflect POTW removal (removal credit requests).
- (c) Third, NWF was skeptical of MDNR's ability to adequately ensure protection of POTWs from interference or pass-through of toxics and MDNR's ability to protect public health, in light of the limited commitment of TCES staff to the pretreatment program.

(3) *Response by the U.S. EPA:* Amendments to Application. MDNR submitted its State NPDES pretreatment

program application amendments, dated November 16, 1984, to the EPA Region V Office, which included amendments to the WRC Part 21 Rules: *Wastewater Discharge Permits—Pretreatment Program*, and a revised program narrative, dated January 4, 1985, that described the administration, implementation, review, compliance, overview, and personnel resource requirements for its pretreatment program. The revised program narrative addressed changes in the staffing and organization, the addition of a pretreatment program coordinator, utilization of available expertise within MDNR for toxicant evaluation (TCES, etc.), financial resources, and legal review of ordinances. In addition, Michigan included revised attachments to the program narrative on funding sources, organizational changes, position descriptions, and personnel qualifications. In these revised attachments, Michigan has formally assigned 1.0 FTE from the TCES staff to the pretreatment program.

The revised pretreatment program narrative clearly delineated the task responsibilities for the TCES Staff, as presented below from pages 4, 8, 9, 10, and 11, of the program narrative.

*Page 4 (Task Assignments).* "Toxic Chemical Evaluation Section, Environmental Services Division, is responsible to review user surveys to determine whether organic toxicants are present in sufficient quantities to warrant control in the POTW's NPDES permit."

#### Task Responsibilities

- Provide technical assistance to SWQ Districts in review of nondomestic user survey submittals.
- Assist SWQ Districts in the review of categorical industry baseline reports.
- Assist SWQ Districts and SWQ Permits Section in toxic chemical evaluations, including determining POTW effluent limits, sludge quality requirements, etc."

*Page 8 (Integration and Coordination with TCES Staff).* "The pretreatment program will be integrated with other state programs related to the control of toxics. This integration will result in a variety of cross-checks and balances among agency staff. For example, major municipal dischargers have been required by their NPDES discharge permits to sample and analyze (on a short term basis) for toxic substances of concern. These substances were chosen by staff of the Toxic Chemical Evaluation and Water Quality Surveillance Sections based on information available at the time the permit was drafted."

"Michigan law requires all industries to annually report use or production of critical materials. By having the District coordinate pretreatment activities with the Toxic Chemical Evaluation Section, better information will be available to improve compliance with the critical materials reporting requirements. This should result in a more effective toxics control program."

NB: "Critical materials" are the inorganic and organic elements or compounds which are listed in the Critical Materials Register compiled by the Michigan Water Resources Commission (Part 9, WRC Rules, promulgated under the authority of Act 245, P.A. 1929, as amended).

*Page 9 (Concern for Public Health).* "Our concern is to ensure that none of these toxicants pass through the POTW in sufficient quantities to create public health and water quality problems. Regulation of these pollutants is accomplished through timely modification of the POTW's NPDES permit. The NPDES permit will set discharge standards and/or monitoring requirements on the POTW."

*Page 9 (Formal, Structured Role for TCES).* "All program elements (requests for removal credits, master plans user surveys, legal authority, and final programs) are submitted to district offices for review and approval. These reviews are aided by guidance and checklists developed in cooperation with EPA. The Districts receive a considerable amount of assistance from the Toxic Chemical Evaluation (TCE) and Water Quality Surveillance (WQS) Sections in the review of User Surveys. These sections advise the Districts as to what organic and inorganic toxicants, respectively, are being or may be discharged at a level of concern to POTW's. This review and the determination of the resultant discharge requirements are done in accordance with Water Resources Commission Rules, particularly R 321.1057."

NB: "Level of concern" refers to the concentration arrived at by an MDNR procedure that utilizes WRC Rule 321.1057 and that evaluates the impacts of a particular toxic pollutant on public health and water quality, and whether that pollutant must be limited in the POTW's NPDES permit.

*Page 10 and 11 (Formal Structures Role for TCES).* "Upon approval of a POTW's pretreatment program responsibility for determining industrial compliance with categorical pretreatment standards, will be delegated to the POTW's with the state providing program overview."



"In the interim prior to POTW program approval, SWQD Districts will be responsible for review of industrial submittals and determination of acceptability. Districts may also receive assistance in this review from Treatment Technology Unit, Water Quality Surveillance Section, Toxic Chemical Evaluation Section and Point Source Studies Section. The following categorical industrial submittals will be received and reviewed by the state, pending POTW program implementation."

- A. Categorical Determination Request.
- B. Baseline Reports, Progress Reports, Final Compliance Reports and Periodic Compliance Reports.
- C. Notice of Slug Loading.
- D. Net/Gross Calculations.

**Status of Michigan Pretreatment Program.** The following number are current as of April 5, 1985, for the status of Michigan's NPDES State pretreatment program:

• Total Programs Required.....	110
• Master Plans Submitted.....	110
• Master Plans Approved.....	103
• Nondomestic User Surveys Submitted.....	110
• Nondomestic user Surveys Approved.....	94
• Legal Authority Documents Submitted.....	108
• Legal Authority Documents Approved.....	85
• Request to Implement Documents Submitted.....	101
• Request to Implement Documents Approved.....	83
• Total Programs Approved as of 4/5/85.....	13
• Total Programs Expected to be Approved by 9/30/85.....	110

The involvement of the TCES staff is minimal in the review and approval of the Request to Implement documents. The bulk of the TCES staff's review of Nondomestic User Surveys has already been accomplished. Consequently, it appears that only 16 Nondomestic User Surveys (and 25 Legal Authority documents) remain for review by the TCES staff. However, due to multi-jurisdictional issues, there may be a few cities what will need to complete the process of reviewing the Nondomestic User Surveys for some of their outlying jurisdictions, during the first two quarters of Fiscal Year 1986 (until about April, 1986). Subsequently, there will be portions of Nondomestic User Surveys for review by the TCES staff as the cities submit these surveys to MDNR for approval. Therefore, it is anticipated that the TCES staff's involvement in the review of these Nondomestic User Surveys will not be completed until the end of Fiscal Year 1986.

**Identifying and Categorizing Industrial User.** EPA, in coordination with the State of Michigan, has temporarily assumed responsibility for the review of the baseline monitoring reports (BMRs). This decision was made in order to allow the State to dedicate all of its pretreatment resources towards the review and approval of pretreatment programs. Once all of the cities required to develop pretreatment programs in the State are reviewed, approved, and incorporated into NPDES permits with the appropriate conditions, the State will be in a better position to actively track BMRs, compliance reports, etc. At a meeting with State Directors on January 9, 1985, Paul D. Zuger requested that EPA begin transferring BMR information to the State and requested a sample of EPA's tracking system, which was subsequently provided. Once the cities in Michigan become the Control Authority with responsibility for the review of BMRs, the responsibility for control of the categorical industries will be shared between MDNR and the cities with approved pretreatment programs.

MDNR has committed itself to provide adequate personnel to operate the program. This includes adequate personnel to review BMRs, a function not specifically addressed by the workload analysis performed by the EPA Region V Office.

**Fundamentally Different Factors Variance Requests.** The review of fundamentally different factors (FDF) variance requests for the State of Michigan is the responsibility of the EPA. Michigan does not have any rules that govern their participation in the review of FDFs. The State recognizes that they can neither deny nor approve FDF requests. On page 4 of the Michigan pretreatment program narrative, the State has offered to: "Review and comment to EPA on FDF requests received from categorical industries". Since EPA has primacy in making final determinations, the State has no mandatory review responsibilities. However, EPA has solicited MDNR's input and MDNR has agreed to provide it to EPA.

**Technical Assistance of TCE and WQS Sections.** The Toxic Chemical Evaluation (TCE) and Water Quality Surveillance (WQS) Sections review the Nondomestic User Surveys and develop toxicant limits that are or will be incorporated into the POTW's NPDES permits. Alternatively, the TCE and WQS Sections develop toxicant monitoring requirements that are placed into the POTW's NPDES permits in order to generate data sufficient to make informed judgements about the potential

for interference or pass-through of those specified toxicants. These toxicant limitations/monitoring requirements are then taken into account when the POTWs set their local limitations that are codified in their sewer use ordinances or in the permits issued to their nondomestic users.

**Explicit Procedure for Local Limitations Development.** The POTWs set their own local limitations in accordance with extensive guidance provided by MDNR. The local limitations development guidance specifies an explicit procedure that must be followed for the calculation of local limits including the use of prescribed mathematical equations, established values for treatment plant interference and water quality, consideration of land application of sludge, evaluation of the actual or potential for pass-through of pollutants, and the review and evaluation of past operational problems. In addition, when the POTWs set their local limitations, they take into account the toxic pollutants identified by the TCE and WQS Sections that are incorporated into their NPDES permits as either toxicant limits or toxicant monitoring requirements.

**MDNR Review of Local Limitations Development.** The MDNR District Offices review the local limits developed by the POTWs and ensure that the POTWs have followed the approved guidance and have taken into account any toxicants identified by the TCE and WQS Sections.

**Monitoring Compliance.** In addition, MDNR has assigned 7.0 FTEs from the TCES staff to the Standards and Waste Load Allocation Program and 2.0 FTEs from the TCES staff to the Compliance Program. Both of these programs have impacts on the pretreatment program. About 2.0 FTEs out of the 9.0 FTEs from the TCES staff assigned to these two programs work on pretreatment related projects. These activities include the following: Reviewing and, where appropriate, revising water quality standards with emphasis on the control of toxic substances; conducting bioassays/biomonitoring to develop water quality standards for toxic pollutants; and ensuring effective implementation of local pretreatment programs by initiating enforcement actions against POTWs which fail to enforce categorical standards requirements in approved local programs and/or initiating direct enforcement action against non-complying categorical industries, where appropriate.

**Summary.** Therefore, based upon the items listed below, we believe that: {1}



NWF's original comments regarding the integration and assignment of TCES staff into the implementation and administration of the pretreatment program is more than adequate to ensure, (a) protection of POTWs from interference of pass-through of toxics, and (b) MDNR's ability to protect public health:

- The revised pretreatment program narrative and attachments clearly delineate the task responsibilities of the TCES staff, and formally integrate TCES staff into the implementation and administration of the pretreatment program.

- Most of the program development work has already been accomplished, and only a small number of removal credit requests are expected to be received for review by MDNR involving the participation of the TCES staff.

- The responsibility for the review of BMR's has temporarily been assumed by EPA. MDNR is currently reassuming this responsibility. By the time this transfer of responsibility is completed, most of the cities required to develop pretreatment programs will have been approved. Thus, the workload of the TCES staff will not be significantly increased.

- The review of FDF variance requests for Michigan is the responsibility of the EPA. Michigan provides review comments to EPA from the SWQD Permits Section, Treatment Technology Unit. This does not directly involve the TCES staff.

- There are about 2.0 additional FTEs from the TCES staff involved in the Standards and Waste Loan Allocation, and Compliance programs that work on pretreatment related projects.

**b. Qualifications of Other MDNR Pretreatment Staff—(1) NWF's Comment:** NWF felt that MDNR had not demonstrated that "qualified personnel were available to carry out the authorities and procedures [to implement the pretreatment program]", as required by 40 CFR 403.10(f)(3) & (g)(2). Therefore, NWF believed that Michigan's application was deficient in terms of the requirements of 40 CFR 403.10(f)(3) "Funding", and 403.10(g)(2) "Content of State Pretreatment Program Submission."

(2) **NWF's Rationale:** This comment stemmed basically from MDNR's reorganization of the Environmental Protection Bureau, which was effective on December 20, 1982. NWF believed that Michigan's application for pretreatment program authorization was difficult to review because the administrative responsibility for the program was described in terms of the superseded administrative structure.

NWF desired a demonstration of the necessary academic credentials and relevant experience of personnel assigned to the program.

(3) **Response by the U.S. EPA:** *Amendments to Application.* MDNR submitted its NPDES State pretreatment program application amendments, dated November 16, 1984, and a revised program narrative, dated January 4, 1985, to the EPA Region V Office that described the administration, implementation, review, compliance, overview, and personnel resource requirements for its pretreatment program. The revised program narrative addressed the changes in the staffing and organization, and the addition of a pretreatment program coordinator. In addition, Michigan included revised attachments to the program narrative with position descriptions, personnel qualifications, and revised organizational charts.

*Demonstration of Qualified Personnel.* In the revised attachments to the amended pretreatment program narrative, MDNR has specified the qualifications required for the various classes of its employees: Aquatic Biologists, Environmental Engineers, General Engineers, Laboratory Scientists, Soil Scientists, and Water Quality Specialists.

There are several levels within each class series that vary based upon the education required, the experience of a given employee, and the work assignment. The following are excerpts taken from the revised attachments to MDNR's NPDES State pretreatment program application amendments. These class series descriptions demonstrate the appropriateness of the specified qualifications.

*Class Series Description: Aquatic Biologist.* "Employees in this class series, as aquatic biologists, participate in, oversee, and direct the performance of a variety of professional biological activities designed to measure the effects of water pollution on aquatic life. Work is performed through the application of a body of knowledge related to professional aquatic appraisal methods, practices, procedures, policies and regulations, and materials and equipment of the aquatic biology service."

*Class Series Description: Environmental Engineer.* "Employees in this class series participate in, oversee, and direct the performance of a variety of environmental engineering activities designed to protect and improve land and water resources, occupational health and air quality in order to provide a clean and healthful environment. Work is performed through the

application of a body of knowledge related to professional environmental engineering methods, practices, procedures, policies and regulations, and materials and equipment of the environmental engineering service."

*Class Series Description: General Engineer.* "Employees in this class series, as engineers 'in-training', participate in the performance of a variety of professional engineering activities. Work is performed through the application of a body of knowledge related to professional engineering methods, practices, procedures, policies and regulations, and materials and equipment of the engineering service."

*Class Series Description: Laboratory Scientist.* "Employees in this class series participate in, oversee, and direct the performance of a variety of tests, analyses, and production and research activities as they relate to chemical, biochemical, and biological samples, specimens, and products. Work is performed through the application of a body of knowledge related to professional scientific laboratory methods, practices, procedures, policies and regulations, and materials and equipment of the laboratory scientist service."

*Class Series Description: Soil Scientist.* "Employees in this class series participate in and direct the performance of a variety of professional activities in soil science designed to survey, classify, and map soils throughout the state. Work is performed through the application of a body of knowledge related to professional methods, practices, procedures, policies and regulations, and materials and equipment of the Soil Scientist Service."

*Class Series Description: Water Quality Specialist.* "Employees in this class series participate in, oversee, and direct the performance of a variety of water quality activities designed to protect and improve the water resources of the state through the application of a body of knowledge related to professional environmental protection methods, practices, procedures, policies and regulations."

*MDNR Staffing Figures.* From EPA's detailed review of the revised attachments to the amended pretreatment program narrative, the following are approximate figures for MDNR staffing of the Environmental Services Division, the Groundwater Quality Division, and the Surface Water Quality Division. These divisions are the one most directly involved in the pretreatment program in Michigan.



Class series	Number of staff
• Aquatic Biologist	22
• Environmental Engineer	64
• General Engineer	4
• Laboratory Scientist	33
• Soil Scientist	4
• Water Quality Specialist	111

**Summary.** Therefore, we believe that Michigan's NPDES State pretreatment program application amendments of November 16, 1984, as revised on January 4, 1985, and the accompanying attachments have completely and fully satisfied NWF's comment that MDNR had not demonstrated that "qualified personnel were available to carry out the authorities and procedures [to implement the pretreatment program]", as required by 40 CFR 403.10(f)(3) & 40 CFR 403.10(g)(2).

**c. MDNR Environmental Protection Bureau Reorganization—(1) NWF's Comment:** In light of the outdated organizational structure relied upon in the Michigan application, NWF felt that EPA's approval of the program should have been delayed pending a clarification of the program responsibilities in the reorganized MDNR Environmental Protection Bureau. NWF believed that the reorganization was so significant in terms of the pretreatment program that it constituted a "changed circumstance" pursuant to 40 CFR 123.62(d) (formerly § 123.13(d)).

**(2) NWF's Rationale:** MDNR's Environmental Protection Bureau was reorganized subsequent to Michigan's submission of its application to EPA, and prior to the public comment period and EPA's approval of Michigan's request. NWF believed that the reorganization significantly altered the administrative structure of the proposed pretreatment program, but the reorganization was not reflected in Michigan's application.

NWF did not feel that the concerns it had expressed with regard to the reorganization could be handled best through in-process changes. NWF believed that the assignment of qualified staff and the development of a viable organizational structure were critical pieces in the administration of MDNR's pretreatment program. NWF felt that the reorganization constituted a "changed circumstance" as that term is used at 40 CFR 123.62(d) (formerly § 123.13(d)). Therefore, NWF felt that EPA had erred in proceeding with its consideration of Michigan's application. As a result, NWF felt that EPA should have required a supplemental program statement which demonstrated the assignment of qualified personnel to the pretreatment

program, prior to its approval of the program revision.

**(3) Response by the EPA:**  
**Reorganization Reflected in Application Amendments.** MDNR submitted its NPDES State pretreatment program application amendments, dated November 16, 1984, and a revised program narrative, dated January 4, 1985, that clarified the program responsibilities in the reorganized MDNR Environmental Protection Bureau, and demonstrated the assignment of qualified personnel to the pretreatment program. In particular, the revised program narrative addressed the changes in the staffing and organization, the addition of a pretreatment program coordinator, and the utilization of available expertise within MDNR for toxicant evaluation. In addition, the revised attachments to the program narrative included position descriptions, personnel qualifications, and revised organizational charts that were current with the reorganization of MDNR's Environmental Protection Bureau. Please also refer to sections (III)(B)(1)(a)(3) and (III)(B)(1)(b)(3) above.

**Summary.** Therefore, we believe that regardless of whether the reorganization of MDNR's Environmental Protection Bureau did or did not constitute a "changed circumstance" pursuant to 40 CFR 123.62(d), necessitating a supplemental program statement, NWF's concern has been completely and fully satisfied by MDNR's NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985.

#### Summary of EPA's Position on NWF's Original Comments

Based upon the responses discussed above (i.e., (III)(B)(1)(a)(3), (III)(B)(1)(b)(3), and (III)(B)(1)(c)(3)), we believe that NWF's original comments have been completely and fully satisfied by MDNR's NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985.

#### 2. Review, Analysis, and Response to NWF's Comments, Dated February 8, 1985, on the Reconsideration of EPA's Approval of Michigan's Pretreatment Program

##### a. Michigan's Revised Pretreatment Rules

**(1) NWF's Comment:** NWF opposed the approval of Michigan's revised application to administer the pretreatment program unless the Michigan Joint Legislative Rules Committee approved the revised pretreatment rules package and it had

been delivered to the *Michigan Register* for publication prior to the court-ordered deadline for the EPA's reconsideration of Michigan's application.

**(2) NWF's Rationale:** NWF and MUCC were represented on the advisory committee which helped MDNR draft the new administrative rules needed to implement the pretreatment program. NWF and MUCC supported these rules in comments submitted to MDNR and in testimony given before the Michigan WRC. These rules were adopted by the WRC on November 15, 1984. However, before they could take effect, these rules had to be approved by the Joint Legislative Rules Committee of the Michigan legislature.

Without these rules, MDNR did not have sufficient legal authority to implement the pretreatment program as required by 40 CFR 403.10(f)(1). Moreover, absent these rules, Michigan's revised NPDES State pretreatment program application did not contain a "complete description of procedures to administer its program in conformance with the requirements of [40 CFR 403.10(g)(1)(iii)]." For example, without these rules MDNR could not enforce pretreatment standards against industrial users, since they are not controlled by State discharge permits or existing State regulations.

##### (3) Response by the EPA:

**Pretreatment Rules Effective.** On March 13, 1985, the proposed pretreatment rules package was approved by the Michigan Joint Legislative Rules Committee. On March 21, 1985, the WRC approved the proposed pretreatment rules. On March 22, 1985, the rules were transmitted to the Office of the Governor of Michigan. On March 26, 1985, EPA requested an extension for 40 days, until May 5, 1985, from the Sixth Circuit Court. On March 26, 1985, the proposed pretreatment rules were filed with the Office of the Secretary of State and with the *Michigan Register*. On April 11, 1985, the proposed amendments to the WRC Part 21 Rules: *Wastewater Discharge Permits—Pretreatment Program* became effective.

**Summary.** Therefore, we believe that NWF's concerns that the pretreatment rules become effective in a timely manner have been adequately addressed by Michigan's expeditious adoption of the pretreatment rules, which were filed with the Michigan Secretary of State on March 26, 1985, and which became fully effective on April 11, 1985.

##### b. "Quality Control" of Pretreatment.



(1) *Local Limits.*—(a) *NWF's Comment:* NWF urged EPA to require a stepped-up training and "quality control" program by MDNR to ensure that it had the procedures required to adequately "review and approve requests for approval of POTW pretreatment programs (40 CFR 403.10(f)(2)(vi))."

(b) *NWF's Rationale:* Where local limits are required to prevent "interference" or "pass-through", POTWs developing pretreatment programs are required to develop these limits as a prerequisite to program approval by the approval authority (40 CFR 403.5).

Based upon NWF's review of several local program submissions, NWF was concerned that MDNR staff were not requiring the generation of data sufficient to make informed judgments about the potential for interference of pass-through. In addition, NWF was concerned that MDNR District staff were not consistently requiring the submission of quantitative analyses of industrial dischargers' wastestreams or of POTWs' influent, effluent, and sludge. Finally, NWF was concerned that MDNR staff were not consistently requiring POTWs to review past operational problems and to consider the effect of their discharge on receiving water quality in evaluating the need for local limits.

Therefore, since MDNR staff must provide a uniform level of scrutiny of the adequacy of industrial user surveys, of POTW's assessment of the need for local limits, and of calculations of such limits, NWF urged the EPA to require a stepped-up training and "quality control" program by MDNR to ensure that this was accomplished.

(c) *Response by the EPA:*

*Utilization of Checklists and Guidance.* MDNR in cooperation with the EPA Region V Office, has developed an extensive series of checklists and guidance for the pretreatment program (master plan, interim elements, and request to implement). The checklists and guidance documents are utilized by MDNR staff when reviewing pretreatment program submittals. These documents ensure that all such reviews are uniform, fair, and that the programs are completely and fully in compliance with the requirements of the General Pretreatment Regulations (40 CFR 403).

*MDNR Training Program.* In addition, within the past year, MDNR has conducted an extensive training program which involved approximately 25 individual training sessions with the District staffs by the MDNR Central Office. These sessions included training in the review of local limitations

development in accordance with the approved guidance, and the procedures as described in Michigan's NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985.

*Revisions to Pretreatment Program Narrative.* MDNR has included in their revised pretreatment program description, narrative portions that delineate the process MDNR will follow in setting limitations at the POTW, and in ensuring that local limitations are developed by POTWs to prevent "interference" or "pass-through". Please refer to the following portions from the Michigan pretreatment program narrative.

*Page 8 (Involvement of TCE and WQS Sections).* "The pretreatment program will be integrated with other state programs related to the control of toxics. This integration will result in a variety of cross-checks and balances among agency staff. For example, major municipal discharges have been required by their NPDES discharge permits to sample and analyze (on a short term basis) for toxic substances of concern. These substances were chosen by staff of the Toxic Chemical Evaluation and Water Quality Surveillance Sections based on information available at the time the permit was drafted. Following a review of the analytical results, effluent concentrations are calculated for those substances that continue to be a concern. A long term sampling program may then be required or an effluent concentration limitation proposed for the discharger. The discharger is notified that the agency intends to include the effluent concentrations as effluent limitations in a future discharge permit. These concentrations would become the basis upon which industrial discharge restrictions would be based in the POTWs pretreatment ordinance. Substances found in low concentrations or absent would not be a continued concern of the agency. The substances found in significant concentrations would be limited through discharge permit modifications."

NB: "Significant concentration" refers to the concentration at which a toxic pollutant reaches a "level of concern". "Low concentration" refers to the concentration at which a toxic pollutant is below a "level of concern". Please refer to the note below on "level of concern".

"Michigan law requires all industries to annually report use of production of critical materials. By having the District coordinate pretreatment activities with the Toxic Chemical Evaluation Section, better information will be available to

improve compliance with the critical materials reporting requirements. This should result in a more effective toxics control program."

NB: "Critical materials" are the inorganic and organic elements or compounds which are listed in the Critical Materials Register compiled by the Michigan Water Resources Commission (Part 9, WRC Rules, promulgated under the authority of Acts 245, P.A. 1919, as amended).

*Page 9 (WRC Rule 321.1057).* "All program elements (requests for removal credits, master plans, user surveys, legal authority, and final programs) are submitted to district offices for review and approval. These reviews are aided by guidance and checklists developed in cooperation with EPA. The Districts receive a considerable amount of assistance from the Toxic Chemical Evaluation (TCE) and Water Quality Surveillance (WQS) Sections in the review of User Surveys. These sections advise the Districts as to what organic and inorganic toxicants, respectively, are being or may be discharged at a level of concern to POTWs. This review and the determination of the resultant discharge requirements are done in accordance with Water Resources Commission Rules, particularly R 321.1057."

NB: "Level of concern" refers to the concentration arrived at by an MDNR procedure that utilizes WRC Rule 321.1057 and that evaluates the impacts of a particular toxic pollutant on public health and water quality, and whether that pollutant must be limited in the POTW's NPDES permit.

*Page 9 (Concern for Public Health).* "Our concern is to ensure that none of these toxicants pass through the POTW in sufficient quantities to create public health and water quality problems. Regulation of these pollutants is accomplished through timely modification of the POTW's NPDES permit. The NPDES permit will set discharge standards and/or monitoring requirements on the POTW."

*Generation of Sufficient Data.* The Toxic Chemical Evaluation (TCE) and Water Quality Surveillance (WQS) Sections review the Nondomestic User Surveys and develop toxicant limits that are or will be incorporated into the POTW's NPDES permit. Alternatively, the TCE and WQS Sections develop toxicant monitoring requirements that are placed into the POTW's NPDES permits in order to generate data sufficient to make informed judgments about the potential for interference or pass-through of those specified toxicants. These toxicant limitations/



monitoring requirements are then taken into account when the POTWs set their local limitations that are codified in their sewer use ordinances or in the permits issued to their nondomestic users.

**Explicit Procedure for Local Limitations Development.** The POTWs set their own local limitations in accordance with extensive guidance provided by MDNR. The local limitations development guidance specifies an explicit procedure that must be followed for the calculation of local limits including the use of prescribed mathematical equations, established values for treatment plant interference and water quality, consideration of land application of sludge, evaluation of the actual or potential for pass-through of pollutants, and the review and evaluation of past operational problems. In addition, when the POTWs set their local limitations, they take into account the toxic pollutants identified by the TCE and WQS Sections that are incorporated into their NPDES permits as either toxicant limits or toxicant monitoring requirements.

**MDNR Review of Local Limitations Development.** The MDNR District Offices review the local limits developed by the POTWs and ensure that the POTWs have followed the approved guidance and have taken into account any toxicants identified by the TCE and WQS Sections.

**EPA Audits.** The EPA Region V Office has conducted pretreatment file audits at four of the nine MDNR District Offices and has found that the State's review comments have improved in timeliness, and are reasonable, appropriate, and thorough. The resulting programs are of high quality, and contain both local limits to control industrial toxicants and monitoring requirements. The EPA Region V Office plans to audit the remaining five District Offices during the third and fourth quarters of the 1985 fiscal year in order to continue to ensure that MDNR's reviews remain satisfactory.

**Summary.** Therefore, based upon the information and procedures summarized below, we believe that NWF's concern regarding quality control to ensure that local limits are adequately developed to prevent pass-through and interference has been fully and completely satisfied by EPA and MDNR:

- The checklist and guidance developed for the review of local limitations development;
- The training program administered to the District Offices by the Central Office;
- The overview conducted by the Central Office in the course of the

training sessions, as well as during its audits of the District staffs' work;

- The advice of applicable MDNR staff (Toxic Chemical Evaluation Section, Water Quality Surveillance Section, etc.) on what organic and inorganic toxicants are being or may be discharged at a level of concern to the POTWs;
- The utilization of WRC Rule R321.1057 in setting effluent limitations at the POTW; and
- The audits and overview of the EPA Region V Office on all phases of program development, including the development of local limitations.

(2) **Legal Authority Reviews—(a) NWF's Comment:** The EPA must require MDNR to develop specific procedures, either generically or on a case-by-case basis, to provide the MDNR District staff with the legal expertise needed to make an independent judgment as to the adequacy of POTWs' legal authorities. These procedures should include rulings from the Michigan Attorney General on the legal questions raised by NWF (multi-jurisdictional issues, and enforcement of categorical pretreatment standards), and the assignment of staff from the Attorney General's Office to respond to questions from the MDNR District staff.

(b) **NWF's Rationale:** The General Pretreatment Regulations require that States proposing to administer the pretreatment program must have "procedures [which] enable the Director to . . . [p]rovide . . . legal assistance to POTWs in developing pretreatment programs (40 CFR 403.10(f)(2)(ii))." Also, Approval Authorities must review POTW pretreatment programs to ensure that POTWs have sufficient legal authority to perform the tasks specified in 40 CFR 403.8(f)(1). In order to fulfill this responsibility, Approval Authorities must: (1) Determine whether a POTW has the necessary legal authorities embodied in a sewer use ordinance or where the municipality does not have the authority to enact such an ordinance, in contracts with nondomestic users; and (2) independently determine that the legal mechanism proposed by a POTW is consistent with Federal, State and local laws.

NWF had identified several recurring problems with the legality of POTWs implementing and enforcing the pretreatment program in the manner they have proposed. NWF had also raised questions about the legality of specific pretreatment program submissions. NWF's concern was that these legal questions would not be resolved until a POTW attempted to enforce its program.

(c) **Response by the EPA: Utilization of Guidance.** MDNR independently reviews POTWs' ordinances and contracts through the utilization of guidance in order to determine whether those ordinances and contracts contain the necessary legal authority, are consistent with Federal and State laws, and are complete. MDNR has committed itself to ensure that this guidance is consistent with Federal requirements and the NPDES State pretreatment program application amendments, dated November 16, 1984, and the revised pretreatment program narrative, dated January 4, 1985.

**MDNR Training Program.** In addition, within the past year, MDNR has conducted an extensive training program which involved approximately 25 individual training sessions with the District staffs by the MDNR Central Office. These sessions included training in legal authority reviews in accordance with the approved guidance, and the procedures as described in Michigan's NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985.

**Utilization of EPA Contractor Assistance.** The EPA Region V Office has provided contract assistance to MDNR in the review of draft sewer use ordinances, legal authority statements, contracts, agreements, and other pertinent legal documents, in order to ensure that the POTWs have the necessary legal authority to operate the pretreatment program.

**Revisions to Program Narrative.** MDNR has included specially redrafted sections to their amended NPDES State pretreatment program application narrative that address NWF's comments on the legal authority reviews (in particular Section III, *Program Implementation*, (a) *Legal Assistance*; and Section IV, *Review of POTW Programs*).

**Page 7 (Involvement of Environmental Enforcement Division and Michigan Attorney General).** "The PPC [Pretreatment Program Coordinator] will provide general guidance to POTWs in terms of providing copies of available regulations and guidance documents. Specific guidance and regulations interpretation will be provided to POTWs upon request on a case-by-case basis. These requests will be coordinated through the PPC, who will contact the Environmental Enforcement Division, Attorney General, or other legal support to obtain the desired confirmation."

**Page 9 (Utilization of EPA Assistance and Guidance).** "The Michigan



Department of Natural Resources (MDNR) has received the assistance of the U.S. EPA in the review of draft sewer use ordinances from POTW's required to develop pretreatment programs. This review is made consistent with guidance developed jointly by the U.S. EPA and the MDNR. The review guidance has been prepared in accordance with 40 CFR 403.8(f) and requires a determination that the proposed ordinance contains all of the necessary elements as set forth in that regulation. This guidance is incorporated into these procedures and is made applicable to these reviews."

MDNR has committed itself to ensure that this guidance is consistent with Federal requirements and the NPDES State pretreatment program application amendments, dated November 16, 1984, and the revised pretreatment program narrative, dated January 4, 1985.

*Page 10 (Independent Authority Review).* "This review includes an independent review that the POTW has the authority to carry out the program and to administer the authorities that are required to be incorporated into the POTW's ordinance by virtue of 40 CFR 403.8(f). Unless MDNR determines that the required proposed ordinance, as applied by the review guidance, and that the POTW's attorney certification fully addresses the POTW's ability to carry out and administer the programs described by 40 CFR 403, MDNR shall not approve the POTW's pretreatment program."

*EPA Audits and Overview.* The EPA Region V Office, through audits and continuing reviews of the MDNR District Offices, has found that the State's reviews of legal authority are consistent with the established procedures, and are in accordance with 40 CFR 403.10(f)(1) and (f)(2). The EPA Region V Office plans to continue its reviews and audits during the third and fourth quarters of the 1985 fiscal year to ensure that MDNR's reviews remain satisfactory.

*Summary.* Therefore, based upon the following items summarized below, we believe that this comment by NWF that MDNR must develop specific procedures to provide the District staff with the legal expertise necessary to make an independent judgment as to the adequacy of POTW's legal authorities, has been fully and completely satisfied by EPA and MDNR:

- The guidance developed for the review of legal authority and sewer use ordinances;
- The training program administered to the District Offices by the Central Office;
- The overview conducted by the

Central Office in the course of the training sessions, as well as during its audits of the District staffs' work;

- The utilization of the EPA contractor for technical reviews of legal authority statements, sewer use ordinances, contracts, agreements, and other pertinent legal documents;
- The revisions to the pretreatment program narrative (as cited above);
- The involvement of the Environmental Enforcement Division and the Michigan Attorney General's Office in legal opinions and determinations; and
- The audits and overview by the EPA Region V Office on all phases of the legal authority reviews.

*c. Modifying POTW's NPDES Permits to Incorporate Pretreatment Conditions*

(1) *NWF's Comment:* Michigan's revised application to administer the pretreatment program must be accompanied by a revision to the 1985 water program plan to require prompt modification of municipal NPDES permits to incorporate approved pretreatment programs. These modifications should be presented to the WRC within 60 days of the approval of the pretreatment programs.

(2) *NWE's Rationale:* The General Pretreatment Regulations require that NPDES permits issued to POTW's developing pretreatment programs must provide that the permit will be "promptly modified or, alternatively, revoked and reissued . . . to incorporate into the POTW's permit an approved POTW pretreatment program. . . ." (40 CFR 403.10(d)(1)).

NWF did not believe that modification of significant municipal permits to incorporate approved pretreatment programs should await elimination of the backlog of expired discharge permits that MDNR has committed to be reissued in 1985. NWF was particularly concerned that municipal dischargers such as the Cities of Detroit, Grand Rapids, and Kalamazoo have their permits promptly modified to ensure that approved pretreatment programs are properly implemented. Until program requirements become enforceable permit conditions, the enforcement options available to EPA, MDNR, and interested citizens may be limited.

(3) *Response by the EPA:*

*Fiscal Year 1985 Water Pollution Control Program Plan.* We believe that this comment by NWF has been addressed by the EPA Region V Office in the MDNR, Surface Water Quality Division, Management Strategy and Water Pollution Program Plan for Fiscal Year 1985 (commonly referred to as the

"Fiscal Year Water Pollution Control Program Plan"). This program plan describes the activities that the State will carry out for water pollution control during the fiscal year, and the staff years, and resources allocated to these activities. These activities are mutually agreed to by both EPA and MDNR, and include MDNR's management objectives for implementing the pretreatment program.

*National Goal and Regional priority.* It is a National goal and a Regional Priority to get all local pretreatment programs approved and to have the approved programs incorporated into NPDES permits by September 30, 1985. This goal was reiterated by Charles H. Sutfin, Director of the EPA Region V Water Division, at the December 20, 1984, meeting of the WRC. Mr. Sutfin stressed the fact that the NPDES permits must be modified to include approved pretreatment programs this fiscal year (1985).

MDNR has committed itself to this National goal and Regional priority in their management objective "PE-2" on page 22 of the "Surface Water Quality Division, Fiscal Year 1985, Management Strategy and Water Pollution Program Plan".

"PE-2. Approve local pretreatment programs. Complete review of local pretreatment programs, incorporate approved pretreatment programs into municipal permits and ensure development, adoption and implementation of adequate programs."

*Incorporation of Approved Pretreatment Program Into POTW's NPDES Permit.* In addition, as stated on page 10 of Michigan's NPDES State pretreatment program application narrative, dated January 4, 1985, MDNR has committed to: "As quickly as possible \* \* \* incorporate[d] [the approved pretreatment program] into the POTW's NPDES permit. If the Pretreatment Program is approved with any conditions, these conditions will also become enforceable requirements of the POTW's NPDES permit."

*Approved Pretreatment Program Permit Language.* The general pretreatment program language that will be incorporated into POTW permits by MDNR, once a pretreatment program is approved, will cover the following five areas: (1) The general pretreatment program goals; (2) specific language prohibiting changes to the program without prior approval; (3) provisions for record retention; (4) reporting requirements for the POTWs; and (5) a schedule for the completion of specific



programmatic tasks in implementing the pretreatment program.

**Opportunity for Public Comment.** We feel that the proper forum for discussing this and similar such concerns is during the opportunity provided by MDNR to comments on the Fiscal Year Water Pollution Control Program Plan. We feel that NWF is asking us to do more than our regulations require. 40 CFR 403.10(d)(1) states that, "... such Permits be promptly modified or, alternatively, revoked and reissued ... to incorporate into the POTW's Permit an approved POTW Pretreatment Program \* \* \* There is no time requirement to modify the permit within 60 days of the program approval.

**Summary.** Therefore, we believe that: (1) This comment by NWF that modifications to municipal NPDES permits be presented to the WRC within 60 days of the approval of the pretreatment program, asks the Agency to go beyond the requirements of the regulations, in particular 40 CFR 403.10(d)(1); and (2) this comment has been adequately responded to and has been completely and fully satisfied with the present National goal and Regional priority of this Agency, and by MDNR's management objective (PE-2) and plan for incorporating approved POTW pretreatment programs into permits, which we believe is adequate and consistent with the applicable Federal requirements.

**Summary and Conclusion.** Based upon EPA's review of the Michigan NPDES State pretreatment program application amendments and the actions taken and programmatic overview conducted by the MDNR and EPA Region V staffs, as described in this notice, we believe that:

(1) NWF's original comments on the Michigan application to administer the pretreatment program have been fully and completely satisfied by the MDNR NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985.

(2) NWF's comments of February 8, 1985, have been completely and fully satisfied by the MDNR NPDES State pretreatment program application amendments, dated November 16, 1984, and as revised on January 4, 1985, and by the actions and programmatic overview of the MDNR and EPA Region V staffs, as previously described in this notice.

#### Federal Register Notice of Approval of State NPDES Programs or Modifications

EPA will provide Federal Register notice of any action by the Agency approving or modifying a State NPDES

program. The following table will provide the public with an up-to-date list of the status of NPDES permitting authority throughout the country.

STATES NPDES PROGRAM STATUS

	Approved State permit program	Approved to regulate Federal Facilities	Approved State pretreatment
Alabama	10-19-79	10-19-79	10-19-79
California	05-14-73	05-05-78	
Colorado	03-27-75		
Connecticut	09-26-73		06-03-81
Delaware	04-01-74		
Georgia	06-28-74	12-08-80	03-12-81
Hawaii	11-28-74	06-01-79	08-12-83
Illinois	10-23-77	09-20-79	
Indiana	01-01-75	12-09-78	
Iowa	08-10-78	08-10-78	06-03-81
Kansas	06-28-74		
Kentucky	09-30-83	09-30-83	09-30-83
Maryland	09-05-74		
Michigan	10-17-73	12-09-78	<sup>1</sup> 06-07-83
Minnesota	06-30-74	12-09-78	07-16-79
Mississippi	05-01-74	01-28-83	05-13-82
Missouri	10-30-74	06-26-79	06-03-81
Montana	06-10-74	06-23-81	
Nebraska	06-12-74	11-02-79	09-07-84
Nevada	09-19-75	06-31-78	
New Jersey	04-13-82	04-13-82	04-13-82
New York	10-28-75	06-13-80	
North Carolina	10-19-75	09-28-84	06-14-82
North Dakota	06-13-75		
Ohio	03-11-74	01-28-83	07-27-83
Oregon	09-26-73	03-02-79	03-12-81
Pennsylvania	06-30-78	06-30-78	
Rhode Island	09-17-84	09-17-84	09-17-84
South Carolina	06-10-75	09-26-80	04-09-82
Tennessee	12-28-77		06-10-83
Vermont	03-11-74		03-16-82
Virgin Islands	06-30-74		
Virginia	03-31-74	02-09-82	
Washington	11-14-73		
West Virginia	05-10-82	05-10-82	05-10-82
Wisconsin	02-04-74	11-26-79	12-24-80
Wyoming	01-30-75	05-18-81	

<sup>1</sup> Reapproved on 04-16-85.

#### VI. Review Under Executive Order 12291 and the Regulatory Flexibility Act

The Office of Management and Budget has exempted this action from the OMB review requirements of Executive Order 12291 pursuant to section 8(b) of that Order.

Pursuant to section 605(d) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), I certify that this State pretreatment program approval will not have a significant impact on a substantial number of small entities. Approval of the Michigan NPDES State pretreatment program established no new substantive requirements, but merely transfers responsibility for administration of the program from EPA to the State.

Dated: April 16, 1985.

Robert Springer,

Deputy Planning and Management Division.

[FR Doc. 85-9986 Filed 4-25-85; 8:45 am]

BILLING CODE 6560-50-M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control Cooperative Agreements; Study of Transmission of Human T- Lymphotropic Virus Type III (HTLV-III) From Infected Mothers to Their Infants; Availability of Funds for Fiscal Year 1985

The Centers for Disease Control (CDC) announces the availability of funds in Fiscal Year 1985 for cooperative agreements for collaborative studies of the transmission of HTLV-III from infected mothers to their infants. This program is authorized by section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)), as amended. The catalog of Federal Domestic Assistance Number is 13.118.

The objectives of this program are as follows:

1. To determine the frequency of and risk factors for transmission of HTLV-III to infants born to infected mothers including those with Acquired Immunodeficiency Syndrome (AIDS), AIDS-related complex (ARC), or who are asymptomatic and seropositive for the virus.

2. To determine the frequency of a risk factors for clinically-evident illness attributable to infection with HTLV-III in the infected infants. Because many of the signs and symptoms associated with AIDS are quite nonspecific in the pediatric population (e.g., lymphadenopathy, failure-to-thrive), infants of both seropositive and seronegative women, matched for confounding factors, would need to be followed.

3. To determine possible modes of transmission from mother to infant and the frequency with which these occur. To meet this objective, infants would need to be tested at birth and at varying intervals thereafter.

4. To determine the effects of pregnancy and HTLV-III infection on immune function by comparing the immune status of infected women before and after pregnancy.

The collaborative and programmatic involvement of the recipient(s) of funds and CDC is as follows:

#### 1. Recipient(s) Activities.

a. Design and conduct a study of the transmission of HTLV-III from infected mothers to their infants.

b. Identify, enroll, and follow a group of pregnant women and their infants.

c. Interview, provide physical examinations, and obtain biological specimens from all study participants.



- d. Design and establish a data management system for the study.
- e. Analyze and publish study results.
- f. Provide or arrange for counselling for participants based on the findings of the study.

#### 2. Centers for Disease Control Activities.

- a. Assist in the development of the study protocol and the design of the interview instrument, including training and pretesting as necessary by individual applicants.
- b. Perform all or a portion of the laboratory studies.
- c. Assist in designing a data management system.
- d. Assist in data analysis and in the presentation and publication of study findings.

Progress reports of cooperative agreement activities will be submitted by the recipient(s) of the funds quarterly for the first year and semiannually thereafter. Financial status reports are required no later than 90 days after the end of each budget period. Final financial status and progress reports are required 90 days after the end of a project period.

Approximately \$500,000 will be available to fund 1-2 cooperative agreements for one year. Applications should be submitted for a 1-year budget period and 2-year project period. Continuation awards within the project period will be made by CDC on the basis of satisfactory progress in meeting project objectives and on the availability of funds. Funding estimates outlined above may vary and are subject to change due to budgetary uncertainties. Cooperative agreement funds may be used to support personnel and to purchase supplies and services directly related to conducting a study of pregnant women and their infants. Funds may not be used to support construction or renovation costs.

Eligible applicants are the official public health agencies of State, city, county, city-county, district and territorial governments, and other public and private organizations which are able to enroll and follow HTLV-III seropositive and seronegative pregnant women and their infants.

Evaluation and ranking of applications will be based on the following factors:

1. The ability of the applicant to enroll and follow approximately 200 pregnant women and their infants. It is estimated that a sample size of approximately 100 seropositive and 100 seronegative pregnant women is needed to determine certain pregnancy and infant outcomes with confidence. Although women of any risk groups would be acceptable

(e.g., women who abuse intravenous drugs, women of Haitian origin), it is preferable that both the seropositive and seronegative cohorts be homogenous with respect to risk factor or at least matched for risk group proportions.

2. The details of how the applicant plans to develop and implement a study of infected women and their infants describing how both infected and noninfected women will be identified, enrolled, and followed.

3. The applicant's understanding of the study objectives and the purpose of the cooperative agreement.

4. The applicant's current activities in HTLV-III research and their relationship with other investigators in the area who may participate in the project.

5. The size, qualifications, and time allocation of the proposed staff and the availability of facilities to be used during the study.

6. How the project will be administered.

7. A proposed schedule for accomplishing the activities of the cooperative agreement including time frames.

Applications must include a narrative which summarizes:

1. The background and need for project support, including information that relates to factors by which the applications will be evaluated.

2. The objectives of the proposed project which are consistent with the purpose of the cooperative agreement and which are measurable and timephased.

3. The methods which will be used to accomplish the objectives. (Of special importance will be the methods used to identify, contact, schedule for interview, and collect biologic specimens from mothers and their infants.)

4. The methods which will be used to evaluate the success of study components.

5. Fiscal information pursuant to utilization of awarded funds in a manner consistent with the purpose and objectives of the project.

6. Any other information that will support the request for assistance.

The original and one copy of the application must be submitted to Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE, Room 321, Atlanta, Georgia 30305, on or before 4:30 pm (e.d.t.) on June 24, 1985.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or
2. Sent on or before the deadline date and received in time for submission to

the independent review group. (Applicants should request a legibly-dated U.S. Postal Service postmark or obtain a legibly-dated receipt from a commercial carrier or U.S. Postal service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

3. Late Applications—applications which do not meet the criteria in either paragraph 1. or 2. immediately above are considered late applications and will not be considered in the current competition.

Applications are not subject to the review requirements of the National Health Planning and Resource Development Act of 1974, as amended, nor to intergovernmental review pursuant to Executive Order 12372.

Information on application procedures, copies of application forms, and other material may be obtained from Nancy Bridger, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE, Room 321, Atlanta, Georgia 30305, or by calling (404) 262-6575 or FTS 236-6575. Technical assistance may be obtained from Martha Rogers, M.D., and Harold W. Jaffe, M.D., AIDS Activity, Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia 30333, telephone (404) 329-3162 or FTS 236-3162.

Dated: April 23, 1985.

William E. Muldoon,

Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 85-10250 Filed 4-25-85; 8:45 am]

BILLING CODE 4160-18-M

## Food and Drug Administration

[Docket No. 85P-0152]

### Canned Collards, Mustard Greens, Spinach, Turnip Greens, and Turnip Greens with Turnips Deviating From Identity Standards; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to the Allen Canning Co. and Heekin Can, Inc., to market test experimental packs of canned collards, mustard greens, spinach, turnip greens, and turnip greens with diced turnips containing added zinc chloride. The purpose of the temporary permit is to



allow the applicant to measure consumer acceptance of the food.

**DATES:** The permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but no later than July 25, 1985.

**FOR FURTHER INFORMATION CONTACT:** F. Leo Kauffman, Center for Food Safety and Applied Nutrition (HFF-214), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0107.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of a standard of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to the Allen Canning Co., 305 East Main St., P.O. Box 250, Siloam Springs, AR 72761, and Heekin Can, Inc., 11310 Cornell Park Dr., Cincinnati, OH 45242.

The permit covers limited interstate marketing tests of experimental packs of canned collards, mustard greens, spinach, turnip greens, and turnip greens with diced turnips. The test products deviate from the standards of identity for canned collards, mustard greens, spinach, turnip greens, and turnips prescribed in 21 CFR 155.200 (certain other canned vegetables) in that they will contain added zinc chloride in an amount reasonably necessary to retain the green color of the product (up to 75 parts per million of zinc in the finished food). The test product meets all requirements of § 155.200, with the exception of the variation.

The permit provides for the temporary marketing of 5,000 cases each of twenty-four number 303 cans and of six number 603 cans of chopped collards, chopped mustard greens, chopped turnip greens, and chopped turnip greens with diced turnips. The permit also provides for the temporary marketing of 10,000 cases of twenty-four number 300 cans and 10,000 cases of six number 603 cans of spinach. The experimental packs of the test products will be distributed in the contiguous 48 States. The test product is to be manufactured at the Allen Canning Co. plants located in Alma, AR 72921, Johnson, AR 72741, Lowell, AR 72745, Siloam Springs, AR 72761, Springdale, AR 72764, and Van Buren, AR 72956.

The principal display panels of the labels state the product names as "Chopped Collard Greens," "Chopped Mustard Greens," "Chopped Turnip Greens," "Chopped Turnip Greens with Diced Turnips," and "Spinach."

Each of the ingredients used is stated on the label as required by the applicable sections of 21 CFR Part 101. The permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but no later than July 25, 1985.

Dated: April 19, 1985.  
Sanford A. Miller,  
Director, Center for Food Safety and Applied Nutrition.  
[FR Doc. 85-10090 Filed 4-25-85; 8:45 am]  
BILLING CODE 4160-01-M

[Docket No. 85P-0150]

**Food for Human Consumption;  
Enriched Bread Deviating From  
Identity Standard; Temporary Permit  
for Market Testing**

**AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to the American Bakeries Co. to market test a bread enriched to the nutrient levels recommended by the National Academy of Sciences, Food and Nutrition Board (FNB), in 1974 (with the exception that iron will remain at the level required by the standard of identity for enriched bread). The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

**DATES:** This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than July 25, 1985.

**FOR FURTHER INFORMATION CONTACT:** F. Leo Kauffman, Center for Food Safety and Applied Nutrition (NFF-214), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0107.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of a standard of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to the American Bakeries Co., 100 Park Ave., New York, NY 10017.

The permit covers limited interstate marketing tests of enriched special formula bread. The test product deviates from the standard of identity for enriched bread (21 CFR 136.115) in that

it will contain in each 2-slice (approximately 2 ounces) serving: (1) 6 percent of the U.S. Recommended Daily Allowance (RDA) of vitamin A, (2) 8 percent of U.S. RDA of vitamin B-6, (3) 8 percent of the U.S. RDA of folic acid, (4) 6 percent of the U.S. RDA of magnesium, and (5) 6 percent of the U.S. RDA of zinc. The test product meets all requirements of § 136.115, with the exception of these deviations.

The permit provides for the temporary marketing of 50,000,000 pounds of the product. The test product is to be manufactured at the American Bakeries Co. plants located in Flushing, NY 11355, and Detroit, MI 48210. The test product will be distributed in the States of Connecticut, Michigan, New Jersey, Ohio, and Pennsylvania.

The principal display panel of the label states the product name as "enriched special formula bread," and each of the ingredients used is stated on the label as required by the applicable sections of 21 CFR Part 101. A side-by-side comparison of the percentage of U.S. RDA's for nutrients in the test product and in regular enriched bread is shown on the label for the applicable nutrients. This permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but no later than July 25, 1985.

Dated: April 19, 1985.  
Sanford A. Miller,  
Director, Center for Food Safety and Applied Nutrition.  
[FR Doc. 85-10089 Filed 4-25-85; 8:45 am]  
BILLING CODE 4160-01-M

[Docket No. 84G-0095]

**Miles Laboratories, Inc.; Filing of Food  
Additive Petition**

**AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Miles Laboratories, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a polyamine-epichlorohydrin resin and glutaraldehyde, together, as fixing agents for immobilizing glucose isomerase enzyme in the production of high fructose corn syrup.

**FOR FURTHER INFORMATION CONTACT:** Leonard C. Gosule, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-9463.



**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 4B3806) has been filed by Miles Laboratories, Inc., Elkhart, IN 46515, proposing that § 173.357 *Materials used as fixing agents in the immobilization of enzyme preparations* (21 CFR 173.357) be amended to provide for the safe use of a polyamine-epichlorohydrin resin and glutaraldehyde, together, as fixing agents in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the *Federal Register* in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: April 18, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-10088 Filed 4-25-85; 8:45 am]

BILLING CODE 4180-01-M

## National Institutes of Health

### Division of Research Grants; Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the following study sections for May through June 1985, and the individuals from whom summaries of meetings and rosters of committee members may be obtained.

These meetings will be open to the public to discuss administrative details relating to study section business for approximately one hour at the beginning of the first session of the first day of the meeting. Attendance by the public will be limited to space available. These meetings will be closed thereafter in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

The Grants Inquiries Office, Division of Research Grants, Westwood Building, National Institutes of Health, Bethesda, Maryland 20205, telephone 301-496-7441 will furnish summaries of the meetings and rosters of committee members. Substantive program information may be obtained from each executive

secretary whose name, room number, and telephone number are listed below each study section. Since it is necessary to schedule study section meetings months in advance, it is suggested that anyone planning to attend a meeting contact the executive secretary to confirm the exact date, time and location. All times are A.M. unless otherwise specified.

Study section	May-June 1985 meetings	Time	Location
Allergy & Immunology, Dr. Eugene Zimmerman, Rm. 320, Tel. 301-496-7380.	June 13-15	8:30	Ramada Inn, Bethesda, MD.
Bacteriology & Mycology-1, Dr. Milton Gordon, Rm. 304, Tel. 301-496-7340.	June 12-14	8:30	Holiday Inn, Georgetown, DC.
Bacteriology & Mycology-2, Dr. William Branche, Jr., Rm. 306, Tel. 301-496-7681.	June 5-7	8:30	Holiday Inn, Georgetown, DC.
Behavioral Medicine, Dr. Joan Rittenhouse, Rm. 232, Tel. 301-496-7109.	June 12-14	9:00	Georgetown Hotel, Washington, DC.
Biochemical Endocrinology, Dr. Norman Gold, Rm. 226, Tel. 301-496-7430.	June 3-6	8:30	Holiday Inn, Bethesda, MD.
Biochemistry-1, Dr. Adolphus P. Toliver, Rm. 318B, Tel. 301-496-7516.	June 17-19	8:30	Georgetown Hotel, Washington, DC.
Biochemistry-2, Dr. Alex Liacouras, Rm. 318A, Tel. 301-496-7517.	June 27-29	8:30	Linden Hill Hotel, Bethesda, MD.
Bio-Organic & Natural Products Chemistry, Dr. Michael Rogers, Rm. A-27, Tel. 301-496-7107.	June 20-22	9:00	Holiday Inn, Golden Gateway, San Francisco, CA.
Biophysical Chemistry, Dr. John B. Wolff, Rm. 236B, Tel. 301-496-7070.	June 13-15	8:30	Room 8, Bldg. 31C, Bethesda, MD.
Bio-Psychology, Dr. A. Keith Murray, Rm. 220, Tel. 301-496-7058.	June 10-14	9:00	Ramada Inn, Bethesda, MD.
Cardiovascular & Pulmonary, Dr. Anthony C. Chung, Rm. 2A-04, Tel. 301-496-7316.	June 12-14	8:30	Linden Hill Hotel, Bethesda, MD.
Cardiovascular & Renal, Dr. Rosemary Morris, Rm. 321, Tel. 301-496-7901.	June 17-19	8:30	Holiday Inn, Bethesda, MD.
Cellular Biology and Physiology-1, Dr. Gerald Greenhouse, Rm. 336, Tel. 301-496-7396.	June 12-14	8:30	Room 4, Bldg. 31A, Bethesda, MD.
Cellular Biology and Physiology-2, Dr. Evelyn Horowitz, Rm. 306, Tel. 301-496-7681.	June 24-26	8:30	Linden Hill Hotel, Bethesda, MD.
Chemical Pathology, Dr. Edmund Copeland, Rm. 353, Tel. 301-496-7078.	June 19-21	8:30	Keystone Intern'l. Resort, Keystone, CO.
Diagnostic Radiology, Dr. Catharine Wingate, Rm. 219B, Tel. 301-496-7650.	June 19-21	8:30	Linden Hill Hotel, Bethesda, MD.
Endocrinology, Dr. Harry Brodie, Rm. 333, Tel. 301-496-7346.	June 16-18	12:00 noon	Holiday Inn, Inner Harbor, Baltimore, MD.
Epidemiology & Disease Control-1, Dr. Phyllis B. Eveleth, Rm. 203C, Tel. 301-496-7246.	June 4-6	8:30	Linden Hill Hotel, Bethesda, MD.
Epidemiology & Disease Control-2, Dr. Ann Schluederberg, Rm. 203B, Tel. 301-496-7246.	June 4-6	8:30	Linden Hill Hotel, Bethesda, MD.
Experimental Cardiovascular Sciences, Dr. Richard Peabody, Rm. 234, Tel. 301-496-7940.	June 25-27	8:00	Ramada Inn, Bethesda, MD.
Experimental Immunology, Dr. David Lavrin, Rm. 222B, Tel. 301-496-7238.	June 12-14	9:00	Holiday Inn, Chevy Chase, MD.
Experimental Therapeutics, Dr. Morris Kelsey, Rm. 221, Tel. 301-496-7597.	June 12-14	8:30	Holiday Inn, Bethesda, MD.
Experimental Virology, Dr. Garrett V. Keeler, Rm. 206, Tel. 301-496-7474.	June 10-12	8:30	Room 8, Bldg. 31C, Bethesda, MD.
General Medicine A-1, Dr. Harold Davidson, Rm. 354A, Tel. 301-496-7797.	June 12-14	8:30	Room 10, Bldg. 31C, Bethesda, MD.
General Medicine A-2, Dr. Donna J. Dean, Rm. 354B, Tel. 301-496-7140.	June 19-21	8:30	Room 6, Bldg. 31C, Bethesda, MD.
General Medicine B, Dr. Antonia Novello, Rm. 322, Tel. 301-496-7730.	June 4-6	8:30	Holiday Inn, Georgetown, DC.
Genetics, Dr. David Remondini, Rm. 349, Tel. 301-496-7271.	June 13-15	9:00	Room 6, Bldg. 31C, Bethesda, MD.
Hearing Research, Dr. Joseph Kimm, Rm. 225, Tel. 301-496-7494.	June 12-14	8:30	Georgetown Hotel, Washington, DC.
Hematology-1, Dr. Clark Lum, Rm. 356A, Tel. 301-496-7508.	June 13-15	8:00	Wellington Hotel, Washington, DC.
Hematology-2, Dr. Bruce Maurer, Rm. 355B, Tel. 301-496-7508.	June 12-14	8:00	Holiday Inn, Georgetown, DC.
Human Development & Aging-1, Dr. Teresa Levitin, Rm. 303, Tel. 301-496-7025.	June 19-21	9:00	Georgetown Hotel, Washington, DC.
Human Development & Aging-2, Dr. Samuel Rawlings, Rm. 305, Tel. 301-496-7640.	June 26-28	9:00	Holiday Inn, Georgetown, DC.
Human Development & Aging-3, Dr. Susan C. Streufert, Rm. 203, Tel. 301-496-9403.	June 17-19	8:30	Linden Hill Hotel, Bethesda, MD.
Human Embryology & Development, Dr. Arthur Hoversland, Rm. 319A, Tel. 301-496-7839.	June 13-15	8:00	Holiday Inn, Chevy Chase, MD.
Immunobiology, Dr. William Stylos, Rm. 222A, Tel. 301-496-7780.	June 19-21	8:30	Holiday Inn, Bethesda, MD.
Immunological Sciences, Dr. Lottie Kornfeld, Rm. 233A, Tel. 301-496-7179.	June 12-14	8:30	Wellington Hotel, Washington, DC.
Mammalian Genetics, Dr. Jerry Roberts, Rm. 349, Tel. 301-496-7271.	June 20-22	8:30	Holiday Inn, Georgetown, DC.
Medicinal Chemistry, Dr. Ronald Dubois, Rm. A-27, Tel. 301-496-7107.	June 26-28	9:00	Holiday Inn, Georgetown, DC.



Study section	May-June 1985 meetings	Time	Location
Metabolism, Dr. Robert Leonard, Rm. 339A, Tel. 301-496-7091.	June 27-29	8:30	Room 8, Bldg. 31C, Bethesda, MD.
Metallobiochemistry, Dr. John A. Beisler, Rm. 310, Tel. 301-496-7733.	June 20-22	8:30	Room 8, Bldg. 31C, Bethesda, MD.
Microbial Physiology & Genetics-1, Dr. Martin Slater, Rm. 238, Tel. 301-496-7183.	June 12-14	8:30	Holiday Inn, Bethesda, MD.
Microbial Physiology & Genetics-2, Dr. Gerald Liddel, Rm. 357, Tel. 301-496-7130.	June 5-7	8:30	Holiday Inn, Rockville, MD.
Molecular & Cellular Biophysics, Dr. Patricia Straat, Rm. 236A, Tel. 301-496-7060.	June 10-12	8:30	Holiday Inn, Chevy Chase, MD.
Molecular Biology, Dr. Donald Disque, Rm. 328, Tel. 301-496-7830.	June 8-8	8:30	Holiday Inn, Georgetown, DC.
Molecular Cytology, Dr. Ramesh Nayak, Rm. 233B, Tel. 301-496-7149.	June 6-8	8:30	Room 7, Bldg. 31C, Bethesda, MD.
Neurological Sciences, Dr. Allen C. Stoolmiller, Rm. 439B, Tel. 301-496-7280.	June 19-22	8:00 p.m.	Room 10, Bldg. 31C, Bethesda, MD.
Neurology A, Dr. Catherine Woodbury, Rm. 326, Tel. 301-496-7095.	June 5-8	8:30	Governor's House, Washington, DC.
Neurology B-1, Dr. Jo Ann McConnell, Rm. 2A03, Tel. 301-496-7422.	June 18-21	8:30	Wellington Hotel, Washington, DC.
Neurology B-2, Dr. Herman Teitelbaum, Rm. 2A05, Tel. 301-496-7422.	June 18-21	8:30	Holiday Inn, Chevy Chase, MD.
Nutrition, Dr. John Schubert, Rm. 204, Tel. 301-496-7178.	June 12-14	8:30	Room 9, Bldg. 31C, Bethesda, MD.
Oral Biology & Medicine-1, Dr. Thomas M. Tarpley, Jr., Rm. 325, Tel. 301-496-7818.	June 11-14	8:30	Linden Hill Hotel, Bethesda, MD.
Orthopedics & Musculoskeletal, Ms.ileen Stewart, Rm. 350, Tel. 301-496-7581.	June 27-29	8:30	Ramada Inn, Bethesda, MD.
Pathobiochemistry, Dr. Sharon Johnson, Rm. A-26, Tel. 301-496-7820.	June 17-19	8:30	Room 8, Bldg. 31C, Bethesda, MD.
Pathology A, Dr. John L. Meyer, Rm. 337, Tel. 301-496-7305.	June 5-7	8:00	Westpark Hotel, Arlington, VA.
Pathology B, Dr. Martin Padarathisingh, Rm. 352, Tel. 301-496-7244.	June 19-21	8:30	Keystone Intern'l. Resort, Keystone, CO.
Pharmacology, Dr. Joseph Kaiser, Rm. 206, Tel. 301-496-7408.	June 25-27	8:30	Holiday Inn, Bethesda, MD.
Physical Biochemistry, Dr. Jeanne Kelley, Rm. 218B, Tel. 301-496-7120.	June 26-28	8:30	Marbury House, Georgetown, DC.
Physiological Chemistry, Dr. Stanley Burrous, Rm. 330B, Tel. 301-496-7837.	June 26-28	8:00	Georgetown Hotel, Washington, DC.
Physiology, Dr. Martin Frank, Rm. 209, Tel. 301-496-7878.	June 10-13	8:30	Holiday Inn, Chevy Chase, MD.
Radiation, Dr. John Zimbrick, Rm. 219A, Tel. 301-496-7073.	June 17-19	9:00	Room 9, Bldg. 31C, Bethesda, MD.
Reproductive Biology, Dr. Dheram Dhindsa, Rm. 307, Tel. 301-496-7316.	June 5-8	8:30	Holiday Inn, Bethesda, MD.
Respiratory & Applied Physiology, Dr. Herbert Yellin, Rm. 218A, Tel. 301-496-7320.	June 10-12	8:30	Linden Hill Hotel, Bethesda, MD.
Sensory Disorders & Language, Dr. Michael Halasz, Rm. 3A-07, Tel. 301-496-7550.	June 12-14	8:30	Holiday Inn, Georgetown, DC.
Social Sciences & Population, Ms. Carol Campbell, Rm. 210, Tel. 301-496-7906.	May 29-31	9:00	Room 7, Bldg. 31C, Bethesda, MD.
Surgery & Bioengineering, Dr. Paul F. Parakkal, Rm. 303A, Tel. 301-496-7506.	June 10-11	8:30	Wellington Hotel, Washington, DC.
Surgery, Anesthesiology & Trauma, Dr. Keith Kraner, Rm. 310B, Tel. 301-496-7771.	June 3-4	8:30	Ramada Inn, Bethesda, MD.
Toxicology, Ms. Faye J. Calhoun, Rm. 205, Tel. 301-496-7570.	June 12-14	8:00	Marbury House, Georgetown, DC.
Tropical Medicine & Parasitology, Dr. Jean Hickman, Rm. 334, Tel. 301-496-1190.	June 10-12	8:00	Holiday Inn, Bethesda, MD.
Virology, Dr. Claire Winstock, Rm. 309, Tel. 301-496-7605.	June 6-8	8:30	Room 9, Bldg. 31C, Bethesda, MD.
Visual Sciences A-1, Dr. Luigi Giacomelli, Rm. 207, Tel. 301-496-7000.	June 3-5	9:00	Linden Hill Hotel, Bethesda, MD.
Visual Sciences A-2, Dr. Jane Hu, Rm. 439A, Tel. 301-496-7310.	June 12-14	8:30	Holiday Inn, Georgetown, DC.
Visual Sciences B, Dr. Earl Fisher, Jr., Rm. 325, Tel. 301-496-7251.	June 12-14	9:00	Linden Hill Hotel, Bethesda, MD.

[Catalog of Federal Domestic Assistance Program Nos. 13.306, 13.333, 13.337, 13.393-13.396, 13.837-13.844, 13.846-13.878, 13.892, 13.893, National Institutes of Health, HHS]

Dated: April 18, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10101 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### Division of Research Resources; Subcommittee on Animal Resources of the Animal Resources Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Subcommittee on Animal Resources, Animal Resources Review Committee, Division of Research Resources, on May 21, 1985, at 8:30 a.m., National Institutes of Health, Building 31, Conference Room 8, 9000 Rockville Pike, Bethesda, Maryland 20205.

The meeting will be open to the public on May 21, from 2:00 p.m. to

approximately 4:00 p.m., for a brief staff presentation on the current status of the Animal Resources Program and the selection of future meeting dates. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on May 21 from 8:30 a.m. to approximately 2:00 p.m. for the review, discussion, and evaluation of individual grant applications submitted to the Laboratory Animal Sciences Program. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. James Augustine, Information Officer, Division of Research Resources, National Institutes of Health, Building 31, Room 5B13, Bethesda, Maryland 20205, (301) 496-5545, will provide summaries of the meeting and rosters of the committee members. Dr. Carl E. Miller, Executive Secretary of the Animal Resources Review Committee, Division of Research Resources, National Institutes of Health, Building 31, Room 5B55, Bethesda, Maryland 20205, (301) 496-5175, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Programs No. 13.306, Laboratory Animal Sciences, National Institutes of Health)

Dated: April 18, 1985.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 85-10099 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### National Cancer Institute; Board of Scientific Counselors, Division of Cancer Prevention and Control; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, May 9-10, 1985, Wilson Hall, Building 1, 9000 Rockville Pike, Bethesda, Maryland 20205. This meeting will be open to the public on May 9, from 8:30 a.m. to 3:00 p.m. and on May 10 from 8:30 a.m. to adjournment to review programs and policies of the Division of Cancer Prevention and Control. Attendance by the public will be limited to space available.



In accordance with provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, a portion of the meeting will be closed to the public on May 9 from approximately 3:00 p.m. to recess for review, discussion and recommendations regarding the disposition of a cooperative agreement project. The discussion regarding the process of the review and subsequent recommendations could reveal personal information concerning individuals associated with the project, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301-496-5708) will provide summaries of the meeting and rosters of committee members upon request.

Mr. J. Henry Montes, Executive Secretary, Board of Scientific Counselors, Division of Cancer Prevention and Control, National Cancer Institute, Blair Building, Room 1A07, National Institutes of Health, Bethesda, Maryland 20205 (Telephone: 301-427-8630) will furnish substantive program information.

Dated: April 17, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10104 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### National Cancer Institute; National Cancer Advisory Board and Board Subcommittees; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Cancer Advisory Board, May 13-15, 1985, National Cancer Institute, Building 31C, Conference Room 6, 6th floor, National Institutes of Health, Bethesda, Maryland 20205. Meetings of Subcommittees of the Board will be held May 12-14 at the times and places listed below. Portions of the Board meeting and its Subcommittees will be open to the public to discuss committee business as indicated in the notice. Attendance by the public will be limited to space available.

Portions of these meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, NCI, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5708) will provide summaries of the meetings and rosters of Board members, upon request.

Mrs. Barbara S. Bynum, Executive Secretary, National Cancer Advisory Board, National Cancer Institute, Building 31, Room 10A03, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5147) will furnish substantive program information.

Name of committee: *National Cancer Advisory Board.*

Dates of meeting: May 13-15, 1985.

Place of meeting: Building 31C, Conference Room 6, 6th floor, National Institutes of Health.

Open: May 13, 8:30 a.m.-recess. May 15, 8:30 a.m.-adjournment.

Agenda: Reports on activities of the President's Cancer Panel and the Director's Report on the National Cancer Institute; Presentation on NIH Peer Review, and a Presentation on NCI Centers Programs; Subcommittee Reports and New Business.

Closed session: May 14, 8:30 a.m.-recess.

Closure reason: To review grant applications.

Name of committee: *Subcommittee on Organ Systems.*

Date of meeting: May 12, 1985.

Place of meeting: Building 31, C Wing, Conference Room 8, Sixth Floor, National Institutes of Health.

Open: May 12, 7:00 p.m.-adjournment.

Agenda: A discussion on the update of the organ systems program.

Name of committee: *Ad hoc Subcommittee on Construction.*

Dated of meeting: May 13, 1985.

Place of meeting: Building 31, C Wing, Conference Room 6, 6th Floor, National Institutes of Health.

Closed: May 13, 5:00 p.m.-adjournment.

Closure reason: To review grant applications.

Name of committee: *Subcommittee on Special Actions for Grants.*

Date of meeting: May 14, 1985.

Place of meeting: Building 31, C Wing, Conference Room 6, 6th Floor, National Institutes of Health.

Closed: May 14, 8:30 a.m.-adjournment.

Closure reason: To review grant applications.

Name of committee: *Subcommittee on Cancer Control for the Year 2000.*

Date of meeting: May 14, 1985.

Place of meeting: Building 31, C Wing, Conference Room 2, 1st Floor, National Institutes of Health.

Open: May 14, 5:00 p.m.-adjournment.

Agenda: To review the report on cancer control for the Year 2000 and tax subsidies on tobacco.

Name of committee: *Subcommittee on Cancer Information.*

Date of meeting: May 14, 1985.

Place of meeting: Building 31, C Wing, Conference Room 6, Sixth Floor, National Institutes of Health.

Open: May 14, 7:30 p.m.-adjournment.

Agenda: A discussion of the cancer information program.

Name of committee: *Subcommittee on Innovations in Surgical Oncology.*

Date of meeting: May 14, 1985.

Place of meeting: Building 31, A Wing, Conference Room 4, 1st Floor, National Institutes of Health.

Open: May 14, 8:00 p.m.-adjournment.

Agenda: A progress report on the surgical oncology program.

(Catalog of Federal Domestic Assistance Program Numbers.)

13.392, project grants in cancer construction.

13.393, project grants in cancer cause and prevention.

13.394, project grants in cancer detection and diagnosis.

13.395, project grants in cancer treatment.

13.396, project grants in cancer biology.

13.397, project grants in cancer centers support.

13.398, project grants in cancer research manpower.

13.399, project grants and contracts in cancer control.)

Dated: April 16, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10100 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### National Eye Institute; Board of Scientific Counselors; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Eye Institute, June 10-11, 1985, Building 31C, Conference Room 7, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public on June 10 from 8:30 a.m. until approximately 3:00 p.m. for general remarks by the Institute's Scientific Director on matters concerning the intramural programs of the National Eye Institute. Attendance by the public will be limited to space available.

In accordance with provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on June 10 from approximately 3:00 p.m. until recess and on June 11 from 8:30 a.m. until adjournment for the review, discussion, and evaluation of individual projects conducted by the Visual Processing Section of the Clinical



Branch. These evaluations and discussions could reveal personal information concerning individuals associated with the projects, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Consequently, this meeting is concerned with matters exempt from mandatory disclosure.

Ms. Kay Valeda, Committee Management Officer, National Eye Institute, Building 31, Room 6A03, National Institutes of Health, Bethesda, Maryland 20205 (301) 496-4903, will provide summaries of the meeting and rosters of committee members.

Substantive program information may be obtained from Dr. Jin Kinoshita, Scientific Director, National Eye Institute, Building 31, Room 6A04, National Institutes of Health, Bethesda, Maryland 20205 (301) 493-7483.

Dated: April 17, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10103 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### **National Eye Institute; National Advisory Eye Council and the Vision Research Program Planning Subcommittee; Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Eye Council, National Eye Institute, May 30-31, 1985, Building 31, Conference Room 8, National Institutes of Health, Bethesda, Maryland, and the subcommittee meeting on May 29, Building 31, Conference Room 3, National Institutes of Health.

This meeting will be open to the public from 9:00 a.m. until approximately 12:00 noon on Thursday, May 30. Following opening remarks by the Director, National Eye Institute, there will be a report on mid-course evaluation of *Vision Research: A National Plan, 1983-1987*, and other presentations by the staff of the Institute.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from approximately 12:00 noon until recess on Thursday, May 30, and from 9:00 a.m. to adjournment on Friday, May 31, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could

reveal confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

There will also be a meeting of the Vision Research Program Planning Subcommittee on Wednesday, May 29 from 7:00 p.m. to 9:00 p.m. to discuss the mid-course evaluation of *Vision Research: A National Plan, 1983-1987*. Attendance by the public will be limited to space available.

Ms. Kay Valeda, Committee Management Officer, National Eye Institute, Building 31, Room 6A03, National Institutes of Health, Bethesda, Maryland 20205 (301) 496-4903, will provide summaries of meetings and rosters of committee members.

Dr. Ronald G. Geller, Associate Director for Extramural and Collaborative Programs, National Eye Institute, Building 31, Room 6A03, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-4903, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.867, Retinal and Choroidal Diseases Research; 13.868, Corneal Diseases Research; 13.869, Cataract Research; 13.870, Glaucoma Research; and 13.871, Sensory and Motor Disorders of Visual Research; National Institutes of Health.

Dated: April 16, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10098 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### **National Heart, Lung, and Blood Institute; Research Manpower Review Committee; Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Research Manpower Review Committee, National Heart, Lung, and Blood Institute, National Institutes of Health on June 20-21, 1985, at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

This meeting will be open to the public on June 20, 1985, from 8:00 p.m. until recess, to discuss administrative details and to hear reports concerning the current status of the National Heart, Lung, and Blood Institute.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on June 21, 1985, from 8:00 a.m. until adjournment for the review, discussion

and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Terry Bellicha, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A21, National Institutes of Health, Bethesda, Maryland 20205, phone (301) 496-4236, will provide a summary of the meeting and a roster of the committee members.

Dr. John L. Fakunding, Executive Secretary, NHLBI, Westwood Building, Room 550, Bethesda, Maryland 20205, phone (301) 496-7361, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, Heart and Vascular Diseases Research; 13.838, Lung Diseases Research; and 13.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: April 16, 1985.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 85-10098 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### **National Institute on Aging; Geriatrics Review Committee; Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Geriatrics Review Committee, National Institute on Aging, on June 24, 25, and 26, 1985, in Building 31, Conference Room 7, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public from 8:30 a.m. to 9:00 a.m. on June 24 for introductory remarks. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on June 24 from 9:00 a.m. to adjournment on June 26 for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June C. McCann, Committee Management Officer, NIA, Building 31,



Room 2C05, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-5898, will provide summaries of meetings and rosters of Committee members as well as substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health)

Dated: April 16, 1985.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 85-10095 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### National Institute on Aging; Aging Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Aging Review Committee, National Institute on Aging, on June 19, 20, and 21, 1985, in Building 31, Conference Room 7, National Institutes of Health, Bethesda, Maryland.

The meeting will be open to the public from 9:00 a.m. on June 19 for introductory remarks. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on June 19 from 9:30 a.m. to adjournment on June 21 for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June C. McCann, Committee Management Officer, NIA, Building 31, Room 2C05, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-5898, will provide summaries of meetings and rosters of Committee members as well as substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health)

Dated: April 16, 1985.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 85-10097 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### National Institute of Allergy and Infectious Diseases; Board of Scientific Counselors; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases, on June 11, 12, and 13 at the Rocky Mountain Laboratories, Hamilton, Montana 59840.

The meeting will be open to the public on June 11 from 9:00 a.m. until 12:30 p.m. During this open session, the permanent staff of the Laboratory of Microbial Structure and Function, the Laboratory of Persistent Viral Diseases, and the Laboratory of Pathobiology will present and discuss their immediate past and present research activities.

In accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting of the board will be closed to the public on June 11 from 1:30 p.m. until recess, on June 12 from 9:00 a.m. until recess and on June 13 from 9:00 a.m. until adjournment for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Rocky Mountain Laboratories, including consideration of personal qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Patricia Randall, Office of Research Reporting and Public Response, National Institute of Allergy and Infectious Diseases, Building 31, Room 7A-32, National Institutes of Health, Bethesda, Maryland 20205, telephone (301) 496-5717, will provide summaries of the meeting and rosters of the Board members.

Dr. Gordon D. Wallace, Acting Executive Secretary, Board of Scientific Counselors, NIAID, National Institutes of Health, Building 10, Room 11C103, telephone (301) 496-3006, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13-301, National Institutes of Health)

Dated: April 17, 1985.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 85-10102 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

#### Commercial/Industrial Activities; Review Schedule

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of Review Schedule.

**SUMMARY:** This notice sets forth the schedule of cost comparison studies for commercial/industrial activities by the National Institutes of Health during Fiscal Year 1985. These studies will be in accordance with Office of Management and Budget Circular A-76.

**FOR FURTHER INFORMATION CONTACT:** Ana Kennedy, Division of Management Policy, National Institutes of Health, Building 31, Room 3B19, 9000 Rockville Pike, Bethesda, Maryland 20205, (301) 496-2461.

**SUPPLEMENTARY INFORMATION:** In accordance with OMB Circular A-76, a cost comparison is scheduled for the audiovisual services to be completed by August 1985. This activity includes projection and audio services, teleconferencing and closed circuit television services and television production services. The activity is located at the National Institutes of Health, Bethesda, Maryland.

Dated: April 23, 1985.

James B. Wyngaarden, M.D.,

Director, National Institutes of Health.

[FR Doc. 85-10336 Filed 4-25-85; 11:15 am]

BILLING CODE 4140-01-M

#### National Arthritis Advisory Board; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Arthritis Advisory Board on June 10, 1985, 1:00 p.m. to 5:00 p.m. at the Jefferson Hotel, 16th and M Street NW., Washington, D.C. 20036. The meeting, which will be open to the public, is being held to discuss the Board's activities and to continue the evaluation of the implementation of the long-range plan to combat arthritis. Attendance by the public will be limited to space available. Notice of the meeting room will be posted in the Hotel lobby.

Certain subcommittees of the Board will meet June 11, 1985. Further information, times and meeting locations of the subcommittees may be obtained by contacting Mr. Raymond Kuehne, Executive Director, National Arthritis Advisory Board, P.O. Box 30174, Bethesda, Maryland 20205, (301) 496-6045. The agenda and rosters of the members can also be obtained from his office. Summaries of the meeting may be obtained by contacting Carole A. Frank, Committee Management Office, NIADDK, National Institutes of Health, Room 9A47, Building 31A, Bethesda, Maryland, 20205, (301) 496-6917.



Dated: April 19, 1985.

Betty J. Beveridge,

NIH Committee Management Officer,

[FR Doc. 85-10105 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

**National Cancer Institute; Board of Scientific Counselors; Division of Cancer Etiology; Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, Division of Cancer Etiology on May 9-10 1985, Building 31, C Wing, Conference Room 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205. The meeting will be open to the public from 1:00 p.m. to recess on May 9, and from 9:00 a.m. to adjournment on May 10, for discussion and review of the Division budget and review of concepts for grants and contracts. Attendance by the public will be limited to space available.

The Board of Scientific Counselors meeting will be closed to the public from 9:00 a.m. to approximately 1:00 p.m. on May 9, 1985, in accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual programs and projects conducted by the Division of Cancer Etiology. These programs, projects, and discussions could reveal personal information concerning individuals associated with the programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. David McB. Howell, Executive Secretary of the Board of Scientific Counselors, Division of Cancer Etiology, National Cancer Institute, Building 31, Room 11A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-6927) will furnish substantive program information.

Dated: April 17, 1985.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 85-10106 Filed 4-25-85; 8:45 am]

BILLING CODE 4140-01-M

**Office of The Secretary**

**Agency Forms Submitted to the Office of Management and Budget for Clearance**

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on April 19, 1985.

**Public Health Service**

**Food and Drug Administration**

Subject: Reporting and Recordkeeping Requirements Imposed by the Methadone Regulations—Reinstatement (0910-0140)

Respondents: Individuals, state/local governments, businesses, non-profit institutions, small businesses  
OMB Desk Officer: Bruce Artim

**Social Security Administration**

Subject: State Agency Budget List of Part-time and Temporary Positions for Disability Programs—SSA 4516—Existing Collection

Respondents: State disability determination staffs

Subject: Supplement to Claim of Person Outside the United States—SSA-21—Revision (0960-0051)

Respondents: Individuals

Subject: State Agency Budget List of Full-time positions for SSA Disability Review—SSA 4515—Existing Collection

Respondents: State disability determination staffs

OMB Desk Officer: Judy A. McIntosh.

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202-245-6511.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503, Attn: (name of OMB Desk Officer).

Dated: April 23, 1985.

Harry A. Hadd,

Acting Deputy Assistant Secretary for Management Analysis and Systems.

[FR Doc. 85-10115 Filed 4-25-85; 8:45 am]

BILLING CODE 4150-04-M

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

**Environmental Impact Statement; Hoopa Valley Indian Reservation, CA**

April 19, 1985.

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice advises the Public that the Draft Environmental Impact Statement (DEIS) for a Proposal to Modify Indian Fishing Regulations to Authorize Commercial Harvesting of Anadromous Fish on the Hoopa Valley Indian Reservation is available for public review. The Hoopa Valley Indian Reservation is located in Humboldt County in Northwestern California.

**DATE:** Written comments are due June 25, 1985.

Comments should be addressed to: Mr. M.W. Babby, Area Director, Sacramento Area Office, 2800 Cottage Way, Sacramento, California 95825.

**FOR FURTHER INFORMATION CONTACT:** Mr. Donald Knapp, Area Environmental Quality Specialist, Sacramento Area Office, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825, Telephone (916) 484-4391.

Individuals wishing copies of this Draft Environmental Impact Statement should contact the above mentioned individual.

**SUPPLEMENTARY INFORMATION:** The Bureau of Indian Affairs has prepared a Draft Environmental Impact Statement on its proposal to modify the fishing regulations for the Hoopa Valley Indian Reservation which will authorize commercial harvesting of anadromous fish by tribal members of the reservation. Prior to authorization, a harvest management plan will be prepared for each species of fish by the Bureau of Indian Affairs in cooperation with the U.S. Fish and Wildlife Service and existing tribal governments. The plans will form the basis for initial regulations. The plans will be reviewed each year and any necessary changes in regulations will be made. In season adjustments or closures will be made by observing run strengths. Each plan will establish the number of fish required to meet spawning goals and the number of fish needed to meet any subsistence or ceremonial needs. Commercial quotas and schedules in the plans will provide tribal members of the reservation with an equal opportunity to the fishery resource. Commercial fishing will be permitted on a species by species basis in those years when subsistence,



ceremonial, and spawning allotments are exceeded by the expected run. In season closure of the commercial fishery will occur if the expected run does not materialize. Alternatives under consideration which were evaluated and analyzed during planning are: (1) No Action, (2) Open Fishing and (3) Phased Commercial Fishing.

Public Meetings will be held at times, locations and on the dates listed below:

Bureau of Indian Affairs, Klamath Field Office Courtroom, Salmon Boulevard, Klamath, California, 10:30 a.m., May 22, 1985;

Ramada Inn, Room 102, 4975 Valley West Boulevard, Arcata, California, 7:00 p.m., May 22, 1985.

Bureau of Indian Affairs, Northern California Agency, Conference Room, Loop Road, Hoopa, California, 10:30 a.m., May 23, 1985.

During the public hearings, oral comments on the contents of the DEIS will be limited to ten minutes and should be accompanied with a written text.

John W. Fritz,

Deputy Assistant Secretary, Indian Affairs.  
[FR Doc. 85-10116 Filed 4-25-85; 8:45 am]

BILLING CODE 4310-02-M

## Bureau of Land Management

### Worland District Grazing Advisory Board; Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463) and the Federal Land Policy and Management Act (Pub. L. 94-579), notice is hereby given of a meeting of the Worland District Grazing Advisory Board to be held at 9:00 a.m., May 30, 1985, in a conference room of the Elks Club, 604 Coburn Ave., Worland, Wyoming.

The agenda for this meeting includes:

1. Amendments to the Grazing Regulations (Subleasing of grazing preference).
2. Update on range improvement project planning.
3. Review of approved FY 1985 range improvement projects.
4. Review of current Allotment Management Plan development.
5. Discussion and Recommendations for proposed FY 1986 and 1987 range improvement projects.
6. Procedures in processing delinquent grazing bills.
7. Range Program Update: Grazing Decisions, Allotment Categorization,

livestock operator consultation and coordination.

8. Assigning maintenance responsibility for rangeland improvements.

9. Opportunity for the public to present information or make comments.

The meeting will be open to the public. Interested persons may make oral statements to the Board during the public comment period, or file written statements for the Board's consideration. Anyone wishing to make an oral statement must notify the District Manager by May 24, 1985.

**DATE:** May 30, 1985, 9:00 a.m.

**ADDRESS:** Elks Club, 604 Coburn Avenue, Worland, Wyoming.

**FOR FURTHER INFORMATION CONTACT:** Chester E. Conard, District Manager, Bureau of Land Management 1700 Robertson Avenue, Worland, Wyoming 82401, (307) 347-9871.

#### **SUPPLEMENTARY INFORMATION:**

Summary minutes of this meeting will be on file in the District Office and available for public inspection (during regular business hours) within 30 days of the meeting.

Chester E. Conard,  
District Manager.

[FR Doc. 85-10179 Filed 4-25-85; 8:45 am]

BILLING CODE 4310-22-M

[Exchange CA-17137]

### Realty Action; Public Lands in Mendocino County, CA

In 48 FR 1632 (April 15, 1983), the following parcels of public land were identified for disposal by exchange CA-13880:

#### **Mount Diablo Meridian, California**

T. 22 N., R. 14 W., Section 9, SW $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
T. 23 N., R. 15 W., Section 32, Lots 3, 4, 5, 6, SE $\frac{1}{4}$ NE $\frac{1}{4}$ .

Containing 211.27 acres, more or less.

These parcels will not be a part of Exchange CA-13880. It has been determined that these parcels remain suitable for disposal and will become part of Exchange CA-17137.

Pursuant to section 206 of the Federal Land Policy and Management Act of October 21, 1976 (90 Stat. 2756), it has been determined that the above described lands along with the below described public low lands are suitable for disposal in Exchange CA-17137:

#### **Mount Diablo Meridian, California**

T. 22 N., R. 14 W., Section 19, Lots 1, 2, 3, 8, NW $\frac{1}{4}$ NE $\frac{1}{4}$ ;  
T. 22 N., R. 15 W., Section 24, Lot 1,  
T. 24 N., R. 16 W., Section 3, Lots 1, 2, 6.

Containing 335.93 acres, more or less.

The State of California State Lands Commission has applied to acquire the above described public lands in exchange for the following described State owned lands:

#### **Mount Diablo Meridian, California**

T. 5 S., R. 36 E., Section 38,  
T. 6 S., R. 37 E., Section 16,  
T. 6 S., R. 37 E., Section 36,  
T. 6 S., R. 38 E., Section 16,  
T. 6 S., R. 38 E., Section 36,  
T. 7 S., R. 35 E., Section 36,  
T. 7 S., R. 37 E., Section 36,  
T. 7 S., R. 38 E., Section 16,  
T. 8 S., R. 36 E., Section 16, E $\frac{1}{2}$ , SW $\frac{1}{4}$ .

Containing 5,600 acres, more or less.

**SUPPLEMENTARY INFORMATION:** All the minerals on the public lands will be transferred to the State. A Mineral Evaluation has been requested on the public lands. If minerals are identified they will be appraised and their value will be included in total value of the exchange.

There will be reserved to the United States in the applied for lands, a right-of-way for ditches and canals constructed by the authority of the United States (43 U.S.C. 945). There will also be a 40-foot wide telephone and telegraph line right-of-way, SAC 045712, reserved to Pacific Telephone and Telegraph Company across Lots 2, 6 in Section 3, T. 24 N., R. 16 W., M.D.M.

The purpose of this exchange is to block up public lands within the Ridgecrest Resource Area to enhance their manageability and resource values.

The publication of this notice in the Federal Register shall segregate the applied for public lands from all other forms of appropriation under the public land laws, including the mining laws, for a period of two years. This exchange is expected to be consummated before the end of that period.

**FOR FURTHER INFORMATION CONTACT:** Bill Dabbs, Realty Specialist, Bureau of Land Management, P.O. Box 940, 555 Leslie Street, Ukiah, CA 95482, Phone: (707) 462-3873. Information for the exchange is available.

**DATES:** For a period of 45 days from the publication of this notice in the Federal Register, interested parties may submit comments to the District Manager, Ukiah District Office, Bureau of Land Management, P.O. Box 940, 555 Leslie Street, Ukiah, CA 95482. Any adverse comments will be evaluated by the California State Director, Bureau of Land Management, who may vacate or modify this realty action and issue a final determination. In the absence of a vacation of modification this realty action will become final determination of the Bureau.



Dated: April 19, 1985.  
 Von W. Manning,  
*Utah District Manager.*  
 [FR Doc. 85-10083 Filed 4-25-85; 8:45 am]  
 BILLING CODE 4310-84-M

## Minerals Management Service

### Development Operations Coordination Document; The Louisiana Land and Exploration Co.

**AGENCY:** Minerals Management Service.

**ACTION:** Notice of the receipt of a proposed development operations coordination document (DOCD).

**SUMMARY:** Notice is hereby given that The Louisiana Land and Exploration Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4417, Block 66, East Cameron Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Cameron, Louisiana.

**DATE:** The subject DOCD was deemed submitted on March 29, 1985. Comments must be received within 15 days of the date of this Notice or 15 days after the Coastal Management Section receives a copy of the DOCD from the Minerals Management Service.

**ADDRESSES:** A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday). A copy of the DOCD and the accompanying Consistency Certification are also available for public review at the Coastal management Section Office located on the 10th Floor of the State Lands and Natural Resources Building, 625 North 4th Street, Baton Rouge, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). The public may submit comments to the Coastal Management Section, *Attention OCS Plans*, Post Office Box 44396, Baton Rouge, Louisiana 70805.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0875.

**SUPPLEMENTARY INFORMATION:** The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS

Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review. Additionally, this Notice is to inform the public, pursuant to § 930.61 of Title 15 of the CFR, that the Coastal Management Section/Louisiana Department of Natural Resources is reviewing the DOCD for consistency with the Louisiana Coastal Resources Program.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected states, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: April 12, 1985.  
 John L. Rankin,  
*Regional Director, Gulf of Mexico OCS Region.*  
 [FR Doc. 85-10085 Filed 4-25-85; 8:45 am]  
 BILLING CODE 4310-MR-M

## INTERSTATE COMMERCE COMMISSION

### Intent to Engage in Compensated Intercompany Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b) (1) that the named corporations intend to provide or use compensated intercompany hauling operations as authorized in 49 U.S.C. 10524(b).

1. Parent corporation and address of principal office: Leggett & Platt, Incorporated, One Leggett Road, Carthage, MO 64836.

2. The wholly-owned subsidiaries which will participate in the intercompany operations and their states of incorporation are as follows:

Bedline Manufacturing Company (a California corporation), 12352 Whittier Boulevard, Whittier, CA 90602  
 Fleet Service Corp. (a California corporation), P.O. Box 4112, Whittier, CA 90607.

I. Parent corporation and address of principal office: Meridian Exploration Corporation, RD #2, P.O. Box 265 D, Cambridge Springs, PA 16403.

II. Wholly-owned subsidiary which will participate in the operations, and State of incorporation:

Subsidiary	State of incorporation
Energy Trucking Company	Pennsylvania.

1. Parent corporation and address of principal office: Ralston Purina Company, 835 South 8th Street, St. Louis, MO 63164.

2. The wholly-owned subsidiaries which will participate in the operations, and states of incorporation.

(a) Purina Mills, Inc. (DE).  
 (b) Agricob, Ltd. (DE) and a wholly owned subsidiary of Purina Mills, Inc.  
 (c) Aid Laboratories, Inc. (DE) and a wholly owned subsidiary of Purina Mills, Inc.  
 (d) Bay-Mor Pet Feeds, Inc. (DE) and a wholly owned subsidiary of Purina Mills, Inc.  
 (e) Chek-Tech, Inc. (DE) and a wholly owned subsidiary of Purina Mills, Inc.  
 (f) Hearty Hound, Inc. (DE) and a wholly owned subsidiary of Purina Mills, Inc.

(g) Kleen Leen, Inc. (DE) and a wholly owned subsidiary of Purina Mills, Inc.

(h) West Willow Farmers Association (PA) and a wholly owned subsidiary of Purina Mills, Inc.

(i) Continental Baking Company (DE).

(j) Bost Bakery, Inc. (NC) and a wholly owned subsidiary of Continental Baking Company.

(k) Bost Bakery, Inc. (NC) and a wholly owned subsidiary of Continental Baking Company.

(l) The Panipus Company (DE) and a wholly owned subsidiary of Continental Baking Company.

(m) Fiber Sales & Development Corporation (DE) and a wholly owned subsidiary of The Panipus Company.

(n) Keystone Resorts Management, Inc. (CO).

(o) Foodmaker, Inc. (DE).

(p) Red and White, Inc. (DE).

(q) Van Can Company (DE).

Kathleen M. King,

*Acting Secretary.*

[FR Doc. 85-10170 Filed 4-25-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-6 (Sub-234)]

### Burlington Northern Railroad Co.; Abandonment in Walla Walla County, WA and Umatilla County, OR; Findings

The Commission has issued a certificate authorizing Burlington Northern Railroad Company to abandon its 14.78 mile rail line between Walla Walla, WA (milepost 0.00) and Milton, OR (milepost 14.78) in Walla Walla County, WA and Umatilla County, OR.

The abandonment certificate will become effective 30 days after this publication unless the Commission also finds that: (1) A financially responsible person has offered assistance through



subsidy or purchase) to enable the rail service to be continued, and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and the applicant no later than 10 days from publication of this Notice. The following notation shall be typed in bold face on the lower left-hand corner of the envelope containing the offer: "Rail Section, AB-OFA." Any offer previously made must be remade within this 10 day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR 1152.27(b).

Kathleen M. King,

Acting Secretary.

[FR Doc. 85-10169 Filed 4-25-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-3 (Sub-49)]

**Missouri Pacific Railroad Co.;  
Abandonment in Cape Girardeau  
County, MO; Findings**

The Commission has issued a certificate authorizing Missouri Pacific Railroad Company to abandon its 3.3-mile rail line between milepost 128.5 and milepost 131.8 in Cape Girardeau County, MO. The abandonment certificate will become effective 30 days after this publication unless the Commission also finds that: (1) A financially responsible person has offered financial assistance (through subsidy or purchase) to enable the rail service to be continued; and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and the applicant no later than 10 days from publication of this Notice. The following notation shall be typed in bold face on the lower left-hand corner of the envelope containing the offer: "Rail Section, AB-OFA." Any offer previously made must be remade within this 10-day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR Part 1152.

Kathleen M. King,

Acting Secretary.

[FR Doc. 85-10171 Filed 4-25-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-12 (Sub-86)]

**Southern Pacific Transportation Co.;  
Abandonment in Polk County, OR;  
Findings**

The Commission has issued a certificate authorizing Southern Pacific Transportation Company to abandon its 2.21-mile rail line between Broadmead (milepost 737.69) and Perrydale (milepost 739.90) in Polk County, OR. The abandonment certificate will become effective 30 days after this publication unless the Commission also finds that: (1) A financially responsible person has offered financial assistance (through subsidy or purchase) to enable the rail service to be continued; and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and the applicant no later than 10 days from publication of this Notice. The following notation shall be typed in bold face on the lower left-hand corner of the envelope containing the offer: "Rail Section, AB-OFA." Any offer previously made must be remade within this 10-day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR Part 1152.

Kathleen M. King,

Acting Secretary.

[FR Doc. 85-10173 Filed 4-25-85; 8:45 am]

BILLING CODE 7035-01-M

**DEPARTMENT OF JUSTICE**

**Lodging of Consent Decree Pursuant  
to the Clean Water Act**

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on April 9, 1985 a proposed Consent Decree in *United States v. Plastics Universal Corporation, et al.*, Civil Action No. 84-183 was lodged with the United States District Court for the Eastern District of Kentucky. The Amended Complaint filed by the United States alleged violations of the Clean Water Act by Plastics Universal Corporation, a wholly owned subsidiary of Adams Resources and Energy Inc., for discharging pollutants during mining operations from point sources located in Bell and Knox Counties, Kentucky into Little Poplar Creek and Stinking Creek, tributaries of the Cumberland River. The Amended Complaint sought injunctive relief to permanently enjoin defendants from discharging without a permit and

civil penalties for past violations of NPDES Permits and Section 301 of the Act, 33 U.S.C. 1311. The proposed Consent Decree requires the defendants to comply with effluent limitations and monitoring requirements required by 40 CFR 434.32 for discharges from all point sources in post-mining areas covered under two (2) NPDES permits until release of reclamation, grading or performance bonds by the Commonwealth of Kentucky. In addition effluent limitations and monitoring requirements established in the previously issued NPDES permits must be complied with for discharges from point sources associated with active mining operations. Plastics Universal Corporation and Adams Resources and Energy, Inc. are required to pay a civil penalty of \$50,000 in settlement of the government's civil penalty claims. Stipulated penalties are provided for non-compliance with the terms and conditions of the Consent Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of publication of this notice comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States v. Plastics Universal Corporation, et al.*, D.J. Ref. 90-1-1-2022.

The proposed Consent Decree may be examined at the Office of the United States Attorney, 326 Federal Building, Limestone and Barr Streets, Lexington, Kentucky 40507, the Region IV Office of the Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365 and at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1515, 10th and Pennsylvania Avenue NW., Washington, D.C. 20530. A copy of the proposed Consent Decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please refer to *United States v. Plastics Universal Corporation, et al.*, D.J. Ref. 90-5-1-1-2022.

F. Henry Habicht II,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 85-10177 Filed 4-25-85; 8:45 am]

BILLING CODE 4410-01-M



## DEPARTMENT OF LABOR

Employment and Training  
Administration

[TA-W-15,534]

Asarco, Inc., Tacoma Smelter, Tacoma,  
WA; Revised Determination on  
Reconsideration

On March 28, 1985 the Department made an Affirmative Determination Regarding Application for Reconsideration for workers and former workers producing blister copper at the Tacoma, Washington Smelter of Asarco, Inc. This determination was published in the Federal Register on April 9, 1985 (50 FR 14034).

The United Steelworkers' application for reconsideration claims that the company's refinery at Amarillo, Texas, the end user of all of Tacoma's production of blister copper, imported blister copper.

The reconsideration findings showed that the Amarillo refinery imported blister copper. The Tacoma smelter was the only smelter of the company that shipped blister copper to Amarillo in 1984. Amarillo initiated the use of imported blister copper in 1984 in volumes that exceeded the decline in Tacoma shipments and that were important relative to Tacoma shipments of blister copper in 1984.

The Tacoma plant ceased all production of blister copper in March 1985 when all production workers were laid off.

## Conclusion

After careful review of the facts obtained on reconsideration. It is concluded that increased imports of articles like or directly competitive with blister copper produced at the Tacoma, Washington smelter of Asarco, Inc., contributed importantly to the decline in sales and production of blister copper and to the total or partial separation of workers and former workers at Asarco's smelter in Tacoma, Washington. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

All workers of the Asarco Inc., Tacoma smelter, Tacoma, Washington who became totally or partially separated from employment on or after October 25, 1983 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of April 1985.

Harold A. Bratt,

Deputy Director, Office of Program  
Management, UIS.

[FR Doc. 85-10182 Filed 4-25-85; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-15,741]

AT&T Consumer Products, AT&T  
Technologies, Inc., Indianapolis, IN;  
Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on February 19, 1985 in response to a worker petition received on January 8, 1985, which was filed by the International Brotherhood of Electrical Workers, Local No. 1504 on behalf of workers at AT&T Consumer Products, AT&T Technologies, Inc., Indianapolis, Indiana.

An active certification covering the petitioning group of workers remains in effect (TA-W-15,063). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 18th day of April 1985.

Marvin M. Fooks,

Director, Office of Trade Adjustment  
Assistance.

[FR Doc. 85-10180 Filed 4-25-85; 8:45 am]

BILLING CODE 4510-30-M

Determinations Regarding Eligibility  
To Apply for Worker Adjustment  
Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period April 15, 1985-April 19, 1985.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated.

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

## Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not

contribute importantly to worker separation at the firm.

TA-W-15,729; AMEDCO Casket  
Hardware, Connersville, IN

In the following cases the investigation revealed that criterion (3) has not been met for the reasons specified.

TA-W-15,710; Crown Zellebach Corp.,  
Chimacum Creek Div., Northwest  
Managed Forest, Port Angeles, WA

Sales declines experienced by the subject firm were attributable to losses in export sales.

TA-W-15,721; Fafnir Bearings,  
Newington, CT

Separations of workers producing ball bearings from the subject firm resulted from a transfer of production to another domestic facility.

The investigation revealed that criterion (2) has not been met for workers producing roller bearings. Sales and production did not decrease as required for certification.

TA-W-15,722; Fafnir Bearings, New  
Britain, CT

Separations of workers producing ball bearings from the subject firm resulted from a transfer of production to another domestic facility.

The investigation revealed that criterion (2) has not been met for workers producing roller bearings. Sales and production did not decrease as required for certification.

## Affirmative Determinations

TA-W-15,725; Rajah Ventures, Limited,  
Grand Junction, CO

A certification was issued covering all workers of the firm separated on or after January 4, 1984 and before December 31, 1984.

TA-W-15,711; Extracorporal, Inc., A  
Johnson & Johnson Co., Norristown,  
PA

A certification was issued covering all workers separated on or after December 18, 1983 and before February 1, 1985.

TA-W-15,716; Mayr Brothers Logging  
Co., Hoquiam, WA

A certification was issued covering all workers separated on or before December 28, 1983.

TA-W-15,708; Phelps Dodge Corp.,  
Morenci Branch Smelter, Morenci,  
AZ

A certification was issued covering all workers separated on or after December 1, 1984 and before February 28, 1985.

TA-W-15,724; Quoddy Manufacturing,  
Auburn, ME



A certification was issued covering all workers of the firm separated on or after December 27, 1983.

TA-W-15,731; B-W Footwear Co., Inc.,  
East Corinth, ME

A certification was issued covering all workers of the firm separated on or after January 18, 1984 and before February 28, 1985.

TA-W-15,726; Roytype, Division of  
Triumph-Adler Co., Newington, CT

A certification was issued covering all workers of the firm engaged in employment related to the assembly of ribbon cartridges separated on or after March 31, 1984.

I hereby certify that the aforementioned determinations were issued during the period April 15, 1985-April 19, 1985. Copies of these determinations are available for inspection in Room 6434, U.S. Department of Labor, 601 D Street, N.W., Washington, D.C. during normal business hours or will be mailed to persons who write to the above address.

Dated: April 23, 1985.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 85-10183 Filed 4-25-85; 8:45 am]

BILLING CODE 4510-30-M

## Office of the Secretary

### Agency Forms Under Review by the Office of Management and Budget (OMB)

#### Background

The Department of Labor, in carrying out its responsibility under the Paperwork Reduction Act (44 U.S.C. Chapter 35), considers comments on the proposed forms and recordkeeping requirements that will affect the public.

#### List of Forms Under Review

On each Tuesday and/or Friday, as necessary, the Department of Labor will publish a list of the Agency forms under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Officer will, upon request, be able to advise members of the public of the nature of any particular revision they are interested in.

Each entry will contain the following information:

The Agency of the Department issuing this form.

The title of the form.

The OMB and Agency form numbers, if applicable.

How often the form must be filled out.

Who will be required to or asked to report.

Whether small businesses or organizations are affected.

An estimate of the number of responses.

An estimate of the total number of hours needed to fill out the form.

The number of forms in the request for approval.

An abstract describing the need for and uses of the information collection.

#### Comments and Questions

Copies of the proposed forms and supporting documents may be obtained by calling the Departmental Clearance Officer, Paul E. Larson, Telephone 202-523-8331. Comments and questions about the items on this list should be directed to Mr. Larson, Office of Information Management, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S-5526, Washington, D.C. 20210. Comments should also be sent to the OMB reviewer, Arnold Strasser, Telephone 202-395-6880, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, NEOB, Washington, D.C. 20503.

Any member of the public who wants to comment on a form which has been submitted to OMB should advise Mr. Larson of this intent at the earliest possible date.

#### Revision

Bureau of Labor Statistics  
CPI Commodities and Services Data  
Collection Forms

1220-0039; BLS 3400, BLS 3400A, BLS  
3400B, BLS 3400C, BLS 3401

Monthly or bimonthly

State or local governments; Businesses or other for-profit; Non-profit institutions; Small businesses or organizations

239,800 responses; 74,507 hours; 5 forms

The Consumer Price Index (CPI) is the nation's leading measure of inflation at the retail level. It is widely used to measure the success of national economic policy and to escalate federal and private payments of many kinds. The Commodities and Services Survey provides the measure of price change for about 80 percent of the CPI. As part of a planned 1987 revision of the CPI, the Bureau of Labor Statistics (BLS) has reformatted the data collection forms to improve the data collection and data capture processes. In addition to the item description and price data that are currently collected, BLS has added

questions about item-specific sales tax rates to the forms.

#### Extension

Employment Standards Administration  
Statement of Earnings

1215-0148; WH-501 and WH-501A

On occasion

Individuals or households; Farms;

Businesses or other for-profit; Small businesses or organizations

2,000,000 responses; 16,666 hours; 2 forms

The Migrant and Seasonal Agricultural Worker Protection Act requires each farm labor contractor, agriculture employer and agricultural association which employs any migrant or seasonal agricultural worker to make and keep for each worker during each pay period specific payroll information and to provide a written copy to each worker and to each person to whom the worker was furnished.

#### Extension

Employment and Training  
Administration

1205-0222; ET Handbook No. 365

Annually

State or local governments

53 Respondents; 25,485 Hours; 22 forms

State Employment Security Agencies (SESAs) use the UI Quality Appraisal annually to assess the accuracy and timeliness of UI operations. Results are used to determine which areas need to be addressed via corrective actions plans in the States' annual Program Budget Plan (PBP).

Signed at Washington, D.C., this 23rd day of April 1985.

Paul E. Larson,

Departmental Clearance Officer.

[FR Doc. 85-10184 Filed 4-25-85; 8:45 am]

BILLING CODE 4510-24-M

## INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

**Proposed Recommendations to the Two Governments for First Stage Treatment and Disposal Facilities for Solution of the Border Sanitation Problem at Tijuana, B.C. and San Diego, CA**

**AGENCY:** United States Section, International Boundary and Water Commission, United States and Mexico.

**ACTION:** Notice of finding of no significant impact.

**SUMMARY:** Based on an environmental assessment, the United States Section finds that the proposed action to enter



into an agreement to solve the border sanitation problem in the Tijuana-San Diego area is not a major Federal action that would significantly affect the quality of the human environment. Rather it would be an improvement to the quality of the environment. Therefore, pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Final Regulations (40 CFR Part 1500); and the United States Section Operational Procedures for Implementing Section 102 of NEPA, published in the **Federal Register** September 2, 1981 (46 FR 44083); the U.S. Section gives notice that an environmental impact statement is not being prepared for the Government of the United States to enter into an agreement with the Government of Mexico, through the International Boundary and Water Commission, to solve the border sanitation problem in the Tijuana-San Diego area.

**FOR FURTHER INFORMATION CONTACT:**  
M.R. Ybarra, Secretary of the United States Section, International Boundary and Water Commission, United States and Mexico, United States Section; 4110 Rio Bravo; El Paso, Texas 79902.  
Telephone: (915) 541-7308, FTS 572-7308.

**SUPPLEMENTARY INFORMATION:**

**Proposed Action**

It is proposed that the Government of the United States enter into an agreement with the Government of Mexico, through the International Boundary and Water Commission, to provide that Mexico construct in its territory adequate first stage treatment and disposal facilities for the City of Tijuana, Baja California and operate and maintain the facilities in such manner that there are no discharges of untreated domestic and industrial waters crossing the boundary into the United States.

The recommendations for the proposed agreement relate to the first stage facilities plan proposed by Mexico for construction, operation and maintenance in its territory for treatment and disposal of 34 million gallons per day of sewage from the City of Tijuana. The first stage facilities plan provides for a pumping plant, conveyance system, treatment facility, and an outfall to the Pacific Ocean 5.6 miles south of the international boundary.

**Alternatives Considered**

Three alternatives were considered: The Proposed Action Alternative provides for Mexico to construct, operate and maintain sewage treatment

in its territory for treatment and disposal of sewage from the City of Tijuana with assurances that there are no discharges of untreated domestic and industrial waters crossing the boundary into the United States.

An alternative of constructing a joint international wastewater treatment plant in the United States near the boundary was proposed by the United States and considered by Mexico. However, for internal reasons Mexico decided against the joint international plant and instead adopted a plan for treatment and disposal works in Mexico.

Under the No Action Alternative, Mexico would be expected to complete construction and put into operation its first stage sewage disposal works for discharges to the ocean without any assurance that Mexico will build, operate and maintain sewage treatment facilities prior to ocean discharge in such a manner that will prevent pollution into the United States.

**Environmental Assessment**

The United States Section prepared an environmental assessment on April 10, 1985.

**Findings of the Environmental Assessment**

The environmental assessment finds that:

1. The agreement would assure, to the extent possible, the prevention of discharges of untreated sewage into the United States and the attendant health hazards and odors associated with raw sewage that have occurred in the south San Diego area.

2. The well-being of citizens of both countries living and traveling in the Tijuana-San Diego area would be improved.

3. The quality of the surf water at the international boundary would be maintained to comply with California standards for primary contact recreation and should result in allowing greater use of beaches along the coast without health risks.

4. The prevention of beach quarantines, as have occurred, would have the positive economic impact of reviving businesses in the beach communities.

5. The water in the Tijuana River estuary would not be polluted by sewage overflows, as have occurred, thereby permitting the full range of uses anticipated in that National Estuarine Sanctuary as well as the adjacent Tijuana Slough National Wildlife Refuge.

6. There would be prevented the adverse impacts, as have occurred, on

critical habitat in the area, affecting species on the endangered species list, and the improved water quality would benefit all area wildlife.

7. The construction of the works, wholly in Mexico, would not affect any archeological or historical sites in the United States territory now on, or proposed for nomination to, the National Register of Historical Places.

8. Therefore, the proposed action to enter into an agreement to solve the border sanitation problem in the Tijuana-San Diego area is not a major federal action that would significantly affect the quality of the human environment.

On the basis of the foregoing and the environmental assessment, the United States Section determines that an environmental impact statement is not required for the Government of the United States to enter into an agreement with the Government of Mexico to solve the border sanitation problem in the Tijuana-San Diego area and hereby provides notice of a finding of no significant impact.

The Finding of No Significant Impact (FONSI) and Final Environmental Assessment (FEA) have been forwarded to the Environmental Protection Agency and to various governmental and non-governmental entities. A limited number of copies of the FONSI and FEA are available for single copy requests at the above address.

Dated: April 18, 1985.

J. F. Friedkin,  
Commissioner.

[FR Doc. 85-10185 Filed 4-25-85; 8:45 am]

BILLING CODE 4710-03-M

**NATIONAL SCIENCE FOUNDATION**

**Advisory Committee for International Programs; Meeting**

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Committee for International Programs.

Dates: May 13, 1985, 10:30 a.m. to 5:00 p.m.; May 14, 1985, 9:00 a.m. to 2:00 p.m.

Place: National Science Foundation, 1800 G Street, NW., Washington, D.C.; May 13—Room 1141, May 14—Room 543.

Type of meeting: Open.

Contact person: Dr. Bodo Bartocha, Director, Division of International Programs, National Science Foundation, Washington, D.C. 20550. Telephone (202) 357-9552.

Summary of minutes: May be obtained from contact person.

Purpose of meeting: To provide advice, recommendations, and oversight related to



support for international cooperation in science and engineering.

#### Agenda

May 13: Consideration of aspects of science, engineering, and foreign policy with speakers from the Department of State and the American Enterprise Institute; discussion of possible future role and organization of international activities.

May 14: STIA and INT program report. Committee discussion and possible recommendations.

**M. Rebecca Winkler,**

*Committee Management Officer.*

April 23, 1985.

[FR Doc. 85-10162 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

#### Advisory Committee for Ocean Sciences (ACOS); Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Ocean Sciences (ACOS).

Date and time: May 23, 24, 1985—9:00 A.M. to 5:00 P.M. each day.

Place: Room 351, National Academy of Sciences, 21st and Pennsylvania Avenue, NW., Washington, DC.

Type of meeting: Open.

Contact person: Dr. M. Grant Gross, Director, Division of Ocean Sciences Room 609, National Science Foundation, Washington, DC. Telephone: (202) 3357-9639.

Summary minutes: May be obtained from the contact person.

Purpose of committee: To provide advice and recommendations concerning oceanographic research and its support by the NSF Division of Ocean Sciences.

#### Agenda

The Committee will hold morning and afternoon Sessions on both days following opening remarks and introductions. The Committee will hear briefings and status reports of current topical interest from various officials and representatives from NSF, other Governmental Departments and Agencies, and other organizations active in ocean science matters. The Committee will also hear reports from several Subcommittees and reflect upon a proper course of action based on the information presented. The Committee will also discuss the current status and future directions of the draft Long-Range Plan for Ocean Sciences, and formulate appropriate guidance and direction for the continuing planning process. The Committee guidance also conduct necessary administrative functions in accordance with established practice with respect to approval of the minutes of the previous meeting determination of the time and place of the

next meeting; as well as any other appropriate business.

**M. Rebecca Winkler,**

*Committee Management Officer.*

April 23, 1985.

[FR Doc. 85-10161 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

#### Advisory Panel for Cell Biology; Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Panel for Cell Biology.

Date and time: May 13, 14 and 15, 1985—8:30 a.m. to 5:00 p.m. each day.

Place: Room 1242A, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Type of meeting: Closed.

Contact person: Antonio H. Romano, Program Director, Cell Biology Program, Room 232, National Science Foundation, Washington, DC 20550. Telephone 202/357-7474.

Purpose of advisory panel: To provide advice and recommendations concerning support for research in cell biology.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b (c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

**M. Rebecca Winkler,**

*Committee Management Officer.*

April 23, 1985.

[FR Doc. 85-10160 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

#### Advisory Panel for Geography and Regional Science; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Science Foundation announces the following meeting:

Name: Advisory Panel for Geography and Regional Science.

Date/time: May 13, 1985—8:30 a.m. to 5:00 p.m., Closed; May 14, 1985—8:30 a.m. to 5:00 p.m., Closed.

Place: National Science Foundation, 1800 G St., NW. (Rm. 628), Washington, DC 20550.

Type of meeting: Closed.

Contact person: Dr. Ronald F. Abler, Director, Geography and Regional Science, National Science Foundation, Washington, DC 20550, Room 312, Phone (202) 357-7326.

Purpose of advisory panel: To provide advice and recommendations concerning research in Regulation and Policy Analysis.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of a proprietary of confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF on July 6, 1979.

**M. Rebecca Winkler,**

*Committee Management Officer.*

April 23, 1985.

[FR Doc. 85-10163 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

#### Advisory Panel for Memory and Cognitive Processes; Meeting:

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting.

Name: Advisory Panel for Memory and Cognitive Processes.

Date and time: May 15-17, 1984: 9:00 a.m.—5:00 p.m. each day.

Place: National Science Foundation, 1800 G St., NW., Washington, D.C. 20550, Room 1141.

Type of meeting: Part open.

Closed—5/15 and 5/17 9:00 a.m. to 5:00 p.m. and 5/16 9:00 a.m. to 10:00 a.m. and 1:00 p.m. to 5:00 p.m.

Open—5/16 10:00 a.m. to 12:00 noon.

Contact person: Dr. Joseph L. Young, Program Director, Memory and Cognitive Processes Program, Room 320, National Science Foundation, Washington, D.C. 20550, telephone (202) 357-9898.

Summary minutes: May be obtained from the Contact Person at the above stated address.

Purpose of meeting: To provide advice and recommendations concerning support for research in memory and cognitive processes.

Agenda: Open—General discussion of the current status and future plans of the Memory and Cognitive Processes Program.

Closed—To review and evaluate research proposals as part of the selection process for awards.



Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

M. Rebecca Winkler,

Committee Management Officer.

April 23, 1985.

[FR Doc. 85-10158 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

### Advisory Panel for Developmental Biology; Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Panel for Developmental Biology.

Date and time: May 16, 17, 18, 1985, starting at 8:30 A.M., to 5:00 P.M.

Place: Room 1242, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550.

Type of meeting: Closed.

Contact person: Dr. Donald E. Fosket, Program Director, Developmental Biology Program; Room 332-H, National Science Foundation, Washington, D.C., 20550. Telephone: 202/357-7989.

Purpose of advisory panel: To provide advice and recommendations concerning support of research in developmental biology.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make determinations by the Director, NSF, on July 6, 1979.

M. Rebecca Winkler,

Committee Management Officer.

April 23, 1985.

[FR Doc. 85-10159 Filed 4-25-85; 8:45 am]

BILLING CODE 7555-01-M

### NUCLEAR REGULATORY COMMISSION

#### General Public Utilities Nuclear Corp.; Environmental Assessment and Notice of Finding of No Significant Environmental Impact

[Docket No. 50320]

The U.S. Nuclear Regulatory Commission (the Commission) is planning to issue an Amendment of Order to Facility Operating License No. DPR-73, issued to General Public Utilities Nuclear Corporation (the licensee), for operation of the Three Mile Island Nuclear Station, Unit 2 (TMI-2), located in Londonderry Township, Dauphin County, Pennsylvania.

#### Environmental Assessment

*Identification of Proposed Action:* The action being considered by the Commission is an Amendment of the Director of Nuclear Reactor Regulation's Order dated February 11, 1980.

This Amendment of Order is being issued in response to General Public Utilities Nuclear Corporation's (GPUNC) letter dated February 15, 1985.

*The Need for the Action:* The Amendment of Order is warranted because of the need to modify the Proposed Technical Specifications (PTS) for future recovery operations at TMI-2. The types of actions to be taken include an increase in the minimum required boron concentration in the RCS; the addition of boron concentration requirements in the Spent Fuel Storage Pool "A" and the Fuel Transfer Canal; the addition of water level and water level monitoring requirements in the Spent Fuel Storage Pool "A" and the Fuel Transfer Canal; and limiting heavy load travel over canisters containing core material.

*Environmental Impacts of the Proposed Actions:* The staff has evaluated the PTS modifications proposed by the Amendment of Order and concluded that it will not result in significant increases in airborne or liquid radioactivity inside the reactor building or in corresponding releases to the environment. There are also no non-radiological impacts to the environment as a result of these actions.

*Alternative to this Action:* Since we have concluded that there is no significant environmental impact associated with the subject Amendment of Order, any alternatives to these changes will have either no significant environmental impact or greater environmental impact. The principal alternative would be to deny the requested actions. This would not reduce significant environmental

impacts of plant operations and would result in the application of overly restrictive regulatory requirements when considering the unique conditions at TMI-2.

*Agencies and Persons Consulted:* The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

*Alternate Use of Resources:* This action does not involve the use of resources not previously considered in connection with the Final Programmatic Impact Statement for TMI-2 dated March 1981.

*Finding of No Significant Impact:* The Commission has determined not to prepare an environmental impact statement for the subject Amendment of Order. Based upon the foregoing environmental assessment, we conclude that this action will not have a significant effect on the quality of the human environment.

For further details with respect to this action see (1) Letter to B.J. Snyder, USNRC, from F.R. Standerfer, GPUNC, Technical Specification Change Request No. 47, dated February 15, 1985; and (2) the Director's Order of February 11, 1980.

All of the above documents are available for inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, DC, and at the Commission's Local Public Document Room at the State Library of Pennsylvania, Government Publications Section, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

For the Nuclear Regulatory Commission.  
Bernard J. Snyder,  
Program Director, Three Mile Island Program  
Office, Office of Nuclear Reactor Regulation.  
April 23, 1985

[FR Doc. 85-10189 Filed 4-25-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-320]

#### General Public Utilities Nuclear Corp. (Three Mile Island Nuclear Station, Unit 2); Amendment of Order

I

GPU Nuclear Corporation, Metropolitan Edison Company, Jersey Central Power and Light Company and Pennsylvania Electric Company (collectively, the licensee) are the holders of Facility Operating License No. DPR-73, which had authorized operation of the Three Mile Island Nuclear Station, Unit 2 (TMI-2) at power levels up to 2772 megawatts thermal. The facility, which is located in



Londonderry Township, Dauphin County, Pennsylvania, is a pressurized water reactor previously used for the commercial generation of electricity.

## II

By Order for Modification of License, dated July 20, 1979, the licensee's authority to operate the facility was suspended and the licensee's authority was limited to maintenance of the facility in the present shutdown cooling mode (44 F.R. 45271). By further Order of the Director, Office of Nuclear Reactor Regulation, dated February 11, 1980, a new set of formal license requirements was imposed to reflect the post-accident condition of the facility and to assure the continued maintenance of the current safe, stable, long-term cooling condition of the facility (45 F.R. 11292).

Although these requirements were imposed on the licensee by an Order of the Director of Nuclear Reactor Regulation, dated February 11, 1980, the TMI-2 license has not been formally amended. The requirements are reflected in the Recovery Mode Proposed Technical Specifications (PTS) presently pending before the Atomic Safety and Licensing Board. The revisions that are the subject of this order do not give the licensee authorizations that may be needed to undertake specific cleanup activities. These activities will require separate consideration by the staff per Section 6.8.2 of the PTS, individual staff safety evaluations and/or licensing actions as appropriate. Hereafter in this Amendment of Order, the requirements in question are identified by the applicable Proposed Technical Specification.

## III

By letter dated February 15, 1985, GPU Nuclear Corporation (GPUNC) proposed changes to the Proposed Technical Specifications (PTS) for Three Mile Island Unit 2.

The licensee proposed to increase the minimum boron concentration in the Reactor Coolant System (RCS) from 3500 ppm to 4350 ppm to insure that for any conceivable core configuration an adequate shutdown margin below criticality is maintained. The licensee also requested the application of minimum and maximum boron concentration limits to the Spent Fuel Storage Pool "A" (SFSPA) and the Fuel Transfer Canal (FTC) of 4350 and 6000 ppm, respectively. In case the water inventories of the RCS, the FTC and the SFSPA communicated because of a leak or valve misalignment, the possibility of

boron dilution of any of these water volumes would be minimized.

The licensee also proposed the addition to the PTS of water level and water level monitoring requirements for the SFSPA and FTC. These requirements would ensure adequate water shielding above fuel canisters. Specific levels will be stated in plant procedures approved by the NRC.

In addition, GPUNC proposed additional load handling requirements for the Fuel Handling Building that would preclude heavy load travel over a fuel canister unless a load drop analysis and associated procedures have been approved by the NRC. Per discussions with GPU, the staff added a requirement that the associated load drop Safety Evaluation be formally submitted to the NRC for approval.

The staff has also added per discussions with the licensee, definitions for Licensed Operator, Senior Licensed Operator and Fuel Handling Senior Reactor Operator.

The associated bases were also modified as requested by the licensee to reflect the above PTS changes.

Other changes proposed by the licensee were applicable to the Recovery Operations Plan (ROP) and are addressed in separate correspondence. Based on discussions herein and those in the attached Safety Evaluation, the staff concurs with the licensee's proposed changes. Minor modifications to the licensee's changes have been made by the staff and concurred with by the licensee as discussed above.

The staff's safety assessment of this matter as discussed above is set forth in the concurrently issued Safety Evaluation. Since the February 11, 1980 Order imposing the Proposed Technical Specifications is currently pending before the Atomic Safety and Licensing Board, the staff will be advising the Licensing Board of this Amendment of Order through a Notice of Issuance of Amendment of Order and a Motion to Conform Proposed Technical Specifications in Accordance Herewith.

It is further determined that the modification does not authorize a change in effluent types or total amounts nor an increase in power level and will not result in any significant environmental impact. In light of this determination and as reflected in the Environmental Assessment and Notice of Finding of No Significant Environmental Impact prepared pursuant to 10 CFR 51.2 and 51.30 through 51.32 issued concurrently herewith, it was concluded that the

action is insignificant from the standpoint of environmental impact and that an environmental impact statement need not be prepared.

## IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Director's Order of February 11, 1980, is hereby revised to incorporate the deletions, additions, and modifications set forth in Enclosure 3 hereto. This Amendment of Order shall be effective on April 30, 1985.

For further details with respect to this action, see (1) Letter to B. J. Snyder, USNRC, from F. R. Standerfer, GPUNC, Technical Specification Change Request 47, Recovery Operations Plan Change Request 27 and (2) the Director's Order of February 11, 1980.

All the above documents are available for inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the Commission's Local Public Document Room at the State Library of Pennsylvania, Government Publications Section, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

Effective Date: May 31, 1985.

Dated at Bethesda, Maryland.

Issuance Date: April 23, 1985.

For the Nuclear Regulatory Commission.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 85-10190 Filed 4-25-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-323]

### Pacific Gas and Electric Co.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from Paragraph III.D.2(b)(ii) of 10 CFR Part 50, Appendix J to Pacific Gas & Electric Company (the applicant). The applicant has applied for a facility operating license for operation of the Diablo Canyon Power Plant, Unit 2 (the facility). This facility is a pressurized water reactor located in San Luis Obispo County, California.

#### Environmental Assessment

*Identification of Proposed Action:* The applicant proposed to perform a full pressure air lock test after cold



shutdown only when maintenance is performed on the air lock which could affect the air lock sealing capability and to substitute the seal leakage test of Paragraph III.D.2(b)(iii) of Appendix J for the full pressure test after cold shutdown.

**The Need for the Proposed Action:** Without the proposed action, either a cumbersome test method must be used or a major design change would be required in order to perform the full pressure air lock test. If an air lock is opened during Mode 5 or 6, paragraph III.D.2(b)(ii) of Appendix J requires that an overall air lock leakage test at not less than  $P_a$  (full pressure test) be conducted prior to plant heatup and startup (i.e., entering Mode 4). The existing air lock doors are so designed that a full pressure of  $P_a$  (47.0 psig) test of an entire air lock can only be performed after strong backs (structural bracing) have been installed on the inner door. Strong backs are needed since the pressure exerted on the inner door during the test is in a direction opposite to that of the accident pressure direction. Installing strong backs, performing the test, and removing strong backs, requires several hours per air lock, during which access through the air lock is prohibited.

**Environmental Impacts of the Proposed Action:** There are no environmental impacts of the proposed action. Whenever the plant is in cold shutdown (Mode 5) or refueling (Mode 6), containment integrity is not required. If the periodic 6-month test of paragraph III.D.2.(b)(i) of Appendix J and the seal test required by paragraph III.D.2(b)(iii) of Appendix J are current, no maintenance has been performed on the air lock that could affect its sealing capability, and the air lock is properly sealed, there is no reason to expect the air lock to leak excessively, even though it has been opened in Mode 5 or Mode 6. Moreover, the proposed exemption does not affect radiological plant effluents nor cause any significant occupational exposures. Thus, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed exemption.

Accordingly, the staff concludes that the applicant's proposed approach of substituting a seal leakage test [as described in paragraph III.D.3(b)(iii)] for the full pressure test of paragraph III.D.2(b)(ii) of Appendix J is acceptable when no maintenance has been performed on an air lock that could affect its sealing capability. Whenever maintenance that could affect its sealing capability has been performed on the air

lock, the requirements of paragraph III.D.2(b)(ii) of Appendix J must still be met by the applicant.

With regard to potential non-radiological impacts, the proposed exemption involves systems located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant non-radiological environmental impacts associated with the proposed exemption.

**Alternative to the Proposed Action:** We have concluded that there is no measurable environmental impact associated with the proposed exemption. The principal alternative would be to deny the requested exemption. This would not reduce environmental impacts of the plant operation.

**Alternative use of Resources:** This action does not involve the use of resources not previously considered in connection with the "Final Environmental Statement Related to the Nuclear Generating Station Diabol Canyon, Units 1 & 2" dated May 1973 and its Addendum dated May 1976.

**Agencies and Persons Consulted:** The NRC staff reviewed the applicant's request and did not consult other agencies or persons.

#### Finding of no Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see Supplement 31 to the Safety Evaluation Report dated April 1985, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at California Polytechnic State University Library, Documents and Maps Department, San Luis Obispo, California 92407.

Dated at Bethesda, Maryland, this 22nd day of April, 1985.

For the Nuclear Regulatory Commission.

Thomas M. Novak,

Assistant Director for Licensing, Division of Licensing.

[FR Doc. 85-10188 Filed 4-25-85; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-327 and 50-328]

#### Tennessee Valley Authority; Consideration of Issuance of Amendments to Facility Operating Licenses and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. DPR-77 and DPR-79, issued to Tennessee Valley Authority (the licensee), for operation of the Sequoyah Nuclear Plant, Units 1 and 2, located in Hamilton County, Tennessee.

On September 20, 1984, a notice of consideration of issuance of amendments was published on proposed changes to the Sequoyah Units 1 and 2 Physical Security Plan as requested in the licensee's letter dated June 13, 1984. The staff's preliminary views indicated that with the proposed changes, the requirements of 10 CFR Part 70 would remain satisfied. After discussions with the NRC staff, the licensee, by letter dated March 27, 1985, proposed compensatory measures to the system. In addition, the licensee has agreed to provide additional operational and test data to support their initial proposal of June 13, 1984, for the perimeter intrusion detection system. The staff will evaluate these data when available, and those from other sources, to determine the adequacy of the initially proposed system.

The staff now believes that the revised security plan with the compensatory measures satisfies the requirements of 10 CFR 73.55.

Before issuance of the proposed license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from an accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of these standards by providing certain examples (48 FR 14870) of actions likely



to involve no significant hazards consideration. One of the examples of actions likely to involve no significant hazards consideration relates to a change which either may result in some increase to the probability or consequences of a previously analyzed accident or may reduce in some way a safety margin, but where the results of the changes are clearly within all acceptable criteria with respect to the system or component specified in the Standard Review Plan. The proposed change involved here is similar to this example in that, although there is some reduction in security effectiveness, a change in being proposed for the implementation of the new security plan which would be a satisfactory alternative to the systems discussed in Regulatory Guide 5.44. Accordingly, the Commission has made an initial determination that the above change does not involve a significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC. 20555, Attn: Docketing and Service Branch.

By May 28, 1985, the licensee may file a request for a hearing with respect to issuance of the amendments to the subject facility operating licenses and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how

that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Elinor G. Adensam: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of the Federal Register notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Herbert S. Sanger, Jr., Esq., General Counsel, Tennessee Valley Authority, 400 Commerce Avenue, E11B33, Knoxville, Tennessee 37902, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).



For further details with respect to this action, see the application for amendments which is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Chattanooga-Hamilton County Bicentennial Library, 1001 Broad Street, Chattanooga, Tennessee 37401.

Dated at Bethesda, Maryland, this 22nd day of April 1985.

For the Nuclear Regulatory Commission,  
Elinor G. Adensam,  
Chief, Licensing Branch No. 4, Division of Licensing.

[FR Doc. 85-10187 Filed 4-25-85; 8:35 am]

BILLING CODE 7590-01-M

## SMALL BUSINESS ADMINISTRATION

### Reporting and Recordkeeping Requirement Under OMB Review

**ACTION:** Notice of Reporting and Recordkeeping Requirement Submitted for OMB Review.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirement to OMB for review and approval, and to publish notice in the *Federal Register* that the agency has made such a submission. **DATE:** Comments must be received on or before May 19, 1985. If you anticipate commenting on a submission but find

that time to prepare will prevent you from submitting comments promptly, advise the OMB reviewer and the Agency Clearance Officer of your intent as early as possible before the comment deadline.

Copies: Copies of forms, request for clearance (S.F. 83), supporting statement, instructions, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

#### FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Elizabeth M. Zaic, Small Business Administration, 1441 L St., NW., Room 200, Washington, D.C. 20416, Telephone: (202) 653-8538

OMB reviewer: Kenneth B. Allen, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3235, New Executive Office Building, Washington, D.C. 20503, Telephone: (202) 395-3785.

#### Information Collection Submitted for Review

Title: 13 CFR 112.9 and 113.5 of SBA's Nondiscrimination Rules and Regulations

Form Nos.: SBA 601, 652, and 793

Frequency: Recordkeeping as necessary  
Description of Respondents: Recipients are required to keep records to enable SBA to do periodic on-site reviews

Annual Recordkeepers: 144,500

Annual Burden Hours: 11,000

Type of Request: Extension

Dated: April 19, 1985.

Elizabeth M. Zaic,  
Chief, Information Resources Management Branch, Small Business Administration.

[FR Doc. 85-10142 Filed 4-25-85; 8:45 am]

BILLING CODE 8025-01-M

#### [License No. 05/05 0119]

### Certco Capital Corp.; License Surrender

Notice is hereby given that Certco Capital Corporation, 6150 McKee Road, Madison, Wisconsin 53707, has surrendered its license to operate as a small business investment company under the Small Business Investment Act of 1958, as amended, (the Act). Certco Capital Corporation was licensed by the Small Business Administration on June 27, 1977.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender was accepted on April 11, 1985, and accordingly, all rights, privileges and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 19, 1985.

Robert G. Lineberry,  
Deputy Associate Administrator for Investment.

[FR Doc. 85-10141 Filed 4-25-85; 8:45 am]

BILLING CODE 8025-01-M

## DEPARTMENT OF TRANSPORTATION

### Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits; Week Ended April 12, 1985

#### Subpart Q Applications

The due date for answers, conforming application, or motions to modify scope are set forth below for each application. Following the answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Date filed	Docket No.	Description
Apr. 17, 1985	43059	People Express Airlines, Inc., c/o Robert E. Cohn, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, NW., Washington, D.C. 20036. Application of People Express Airlines, Inc. pursuant to section 401 of the Act and Subpart Q of the Regulations for a certificate of public convenience and necessity authorizing it to engage in scheduled foreign air transportation of persons, property and mail over the following routes: Between a point or points in the United States, and a point or points in Ireland (Shannon) Belgium, the Federal Republic of Germany, the Netherlands, Luxembourg, and Switzerland. Conforming Applications, Motions to Modify Scope and Answers may be filed by May 15, 1985.
Apr. 19, 1985	43063	Eastern Air Lines, Inc., Miami International Airport, Miami, Florida 33148. Application of Eastern Air Lines, Inc. pursuant to section 401 of the Act and Subpart Q of the Regulations applies for amendment of its certificate of public convenience and necessity for Route 165 so as to authorize service between the terminal point Miami, Florida and the terminal point Madrid, Spain. Conforming Applications, Motions to Modify Scope and Answers may be filed by May 17, 1985.
Do	43064	Air Specialties Corp., d/b/a Total Air, c/o Robert E. Cohn, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, NW., Washington, D.C. 20036. Application of Air Specialties Corp., d/b/a Total Air pursuant to Section 401 of the Act and Subpart Q of the Regulations requests issuance of a certificate of public convenience and necessity which would authorize it to engage in the interstate and overseas scheduled air transportation of passengers, property and mail between all points in the United States, its territories and possessions. Conforming Applications, Motions to Modify Scope and Answers may be filed by May 17, 1985.



Phyllis T. Kaylor,  
Chief, Documentary Services Division.  
[FR Doc. 85-10125 Filed 4-25-85; 8:45 am]  
BILLING CODE 4910-82-M

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Environmental Impact Statement; La Porte County, Porter County, City of Michigan City, IN

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project located in LaPorte County, Porter County and the City of Michigan City, Indiana.

**FOR FURTHER INFORMATION CONTACT:** Mr. James E. Threlkeld, District Engineer, Federal Highway Administration, Federal Office Building, Room 254, 575 North Pennsylvania Street, Indianapolis, Indiana 46204. Phone (317) 269-7474.

**SUPPLEMENTARY INFORMATION:** The FHWA in cooperation with the Indiana Department of Highways (IDOH) will prepare an environmental impact statement (EIS) on a proposal to construct a 3.5 mile section of new 4-lane roadway between Interstate Route 94 and US Route 12 on the west side of Michigan City. The proposed roadway will be located within a 1.0 mile wide corridor generally following along and to the east of the LaPorte County-Porter County line. The proposed action will include a new interchange on Interstate Route 94 at the LaPorte County-Porter County line.

Completion of this proposed action will permit a direct south to north access from Interstate Route 94 to the planned East Unit Transit Center at the Indiana Dunes National Lakeshore. This proposed action will also improve access to the Lake Michigan recreational areas located within the Indiana Dunes National Lakeshore and in Michigan City. A reduction in traffic congestion along US Route 421 (Franklin Street) in Michigan City is also anticipated.

Various alternative alignments within the 1.0 mile by 3.5 mile corridor will be developed and evaluated in the EIS. Grade separation structures at the US Route 20 intersection and at three (3) railroad crossings will be considered. The evaluation of alternatives in the EIS will include a do-nothing action.

To ensure that the full range of issues related to this proposed action are addressed and that all significant issues are identified, those agencies, groups or individuals affected by or interested in the proposed action are invited to participate by sending their written comments to the FHWA. A formal Scoping Meeting will be held at 10:00 A.M., May 23, 1985, at the offices of the IDOH, Room 1201, State Office Building, 100 North Senate Avenue, Indianapolis, Indiana 46204. Public Information Meetings will be held during the early development phase of the proposed project. Dates and locations of such meetings will be advertised in newspapers having local distribution within the project area.

(Catalog of Federal Domestic Assistance Program No. 20.205 [Highway Research, Planning and Construction], the provisions of Executive Order 12372 regarding State and local inter-governmental review of Federal and Federally-assisted programs and projects apply to this program)

Issued on: April 18, 1985.

James E. Threlkeld,  
District Engineer.

[FR Doc. 85-10084 Filed 4-25-85; 8:45 am]

BILLING CODE 4910-22-M

## DEPARTMENT OF THE TREASURY

### Customs Service

[T.D. 85-73]

#### Tuna Fish—Tariff-Rate Quota

The tariff-rate quota for the calendar year 1985, on tuna classifiable under item 112.30, tariff schedules of the United States (TSUS).

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** Announcement of the quota quantity for tuna for Calendar Year 1985.

**SUMMARY:** Each year the tariff-rate quota for tuna fish described in item 112.30, TSUS, is based on the United States pack of canned tuna during the preceding calendar year.

**EFFECTIVE DATES:** The 1985 tariff-rate quota is applicable to tuna fish entered, or withdrawn from warehouse, for consumption during the period January 1, through December 31, 1985.

**FOR FURTHER INFORMATION CONTACT:** William J. Wagner, III, Head, Quota Section, General Programs Branch, Duty Assessment Division, Office of Commercial Operations, U.S. Customs Service, Washington, D.C. 20229 (202-566-8592).

It has now been determined that 97,495,800 pounds of tuna may be entered for consumption or withdrawn from warehouse for consumption during the Calendar Year 1985, at the rate of 6 percent ad valorem under item 112.30, TSUS. Any such tuna which is entered, or withdrawn from warehouse, for consumption during the current calendar year in excess of this quota will be dutiable at the rate of 12.5 percent ad valorem under item 112.34, TSUS.

Dated: April 23, 1985.

William von Raab,

Commissioner of Customs

[FR Doc. 85-10143 Filed 4-25-85; 8:45 am]

BILLING CODE 4820-02-M

### Public Information Collection Requirements Submitted to OMB for Review

Dated: April 23, 1985.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB (listed by submitting bureau(s)), for review and clearance under the Paperwork Reduction Act of 1960, Pub. L. 96-511. Copies of these submissions may be obtained by calling the Treasury Bureau Clearance Officer listed under each bureau. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of each bureau's listing and to the Treasury Department Clearance Officer, Room 7221, 1201 Constitution Avenue, NW., Washington, D.C. 20220.

#### Internal Revenue Service

OMB Number: New

Form Number: IRS Form 8411

Type of Review: New

Title: Bounce-Back Cards for Theaters

OMB Number: 1545-0123

Form Number: IRS Form 1120, Schedules D and PH

Type of Review: Revision

Title: U.S. Corp. Income Tax Return, Capital Gains and Losses, Comp. of U.S. Pers. Holdings Co. Tax

OMB Number: 1545-0351

Form Number: IRS Forms 3975, 2333, 2333E, 2333EA, 2333R, 2333S, 2333T and 2333X

Type of Review: Revision

Title: Tax Practitioner Mailing File (TPMF) Order Fulfillment Program

Clearance Officer: Garrick Shear, (202)

566-6150, Room 5571, 1111

Constitution Avenue, NW.,

Washington, D.C. 20224

OMB Reviewer: Robert Neal, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive



Office Building, Washington, D.C.  
20503.

#### U.S. Customs Service

OMB Number: 1515-0042

Form Number: CF 4457

Type of Review: Extension

Title: Certificate of Registration for  
Personal Effects Taken Abroad

Clearance Officer: Vince Olive, (202)  
566-9181, U.S. Customs Service, Room  
2130, 1301 Constitution Avenue, NW.,  
Washington, D.C. 20229

OMB Reviewer: Milo Sunderhauf, (202)  
395-6880, Office of Management and  
Budget, Room 3208, New Executive  
Office Building, Washington, D.C.  
20503.

Joseph F. Maty,

Departmental Reports Management Office.

[FR Doc. 85-10117 Filed 4-25-85; 8:45 am]

BILLING CODE 4810-25-M

#### UNITED STATES INFORMATION AGENCY

**Grants Program for Private Not-for-  
Profit Organizations in Support of  
International Educational and Cultural  
Activities**

#### Correction

In FR Doc. 85-9688 beginning on page

16038 in the issue of Tuesday, April 23,  
1985, make the following correction on  
page 16039: In the first column, in the  
seventh line, "120 days" should read "20  
days".

BILLING CODE 1505-01-M

#### OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

#### Implementation of Proclamation Concerning Duty-Free Treatment for Certain Articles in Trade in Civil Aircraft

**AGENCY:** Office of the United States  
Trade Representative.

**ACTION:** Notice.

**SUMMARY:** This notice provides the  
effective date for implementation of  
duty-free treatment for certain articles  
in trade in civil aircraft.

**EFFECTIVE DATE:** April 29, 1985.

**FOR FURTHER INFORMATION CONTACT:**  
Alexander Platt, Associate General  
Counsel, Office of the United States  
Trade Representative (202) 395-7305.

**SUPPLEMENTARY INFORMATION:** Section  
234 of the Trade and Tariff Act of 1984  
(Pub. L. 98-573) authorized the President  
to proclaim modifications in enumerated

items of the Tariff Schedules of the  
United States (TSUS) (19 U.S.C. 1202) in  
order to provide duty-free coverage  
comparable to the expanded coverage  
provided by all other signatories to the  
Agreement on Trade in Civil Aircraft.  
Pursuant to that section, Presidential  
Proclamation 5291 of December 28, 1984  
(50 FR 223) proclaimed modifications in  
various TSUS items and directed the  
United States Trade Representative to  
determine and publish the effective date  
of such modifications.

Accordingly, I have determined that  
the expanded coverage provided by  
other signatories to the Agreement is  
comparable to the expanded coverage to  
be provided by the United States under  
the terms of Presidential Proclamation  
5291. I have further determined that the  
effective date of the additional duty-free  
treatment to be accorded by the United  
States shall be effective with respect to  
articles entered, or withdrawn from  
warehouse for consumption, on or after  
the day after publication of this Notice.

William E. Brock,

United States Trade Representative.

[FR Doc. 85-10192 Filed 4-25-85; 8:45 am]

BILLING CODE 3190-01-M



# Sunshine Act Meetings

Federal Register

Vol. 50, No. 81

Friday, April 26, 1985

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

## CONTENTS

	Item
Equal Employment Opportunity Commission	1
Federal Energy Regulatory Commission	2
Federal Maritime Commission	3
Federal Reserve System	4
Legal Services Corporation	5
National Foundation on the Arts and Humanities	6
Postal Service	7
Securities and Exchange Commission	8

### 1

#### EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

**DATE AND TIME:** Tuesday, May 7, 1985, 9:30 a.m. (eastern time).

**PLACE:** Clarence M. Mitchell, Jr., Conference Room No. 200-C on the 2nd Floor of the Columbia Plaza Office Building, 2401 "E" Street, NW., Washington, D.C. 20507.

**STATUS:** Part will be open to the public and part will be closed to the public.

#### MATTERS TO BE CONSIDERED:

1. Announcement of Notation Vote(s)
2. A Report on Commission Operations (Optional)
3. Proposed Compliance Manual §12, Involvement of the Legal Unit in the Administrative Process
4. Proposed Compliance Manual §27, Pre-Determination Interviews
5. Proposed Compliance Manual §40, Issuance of Cause Determination
6. Proposed Compliance Manual §88, Conciliation Failures; Litigation Review and Private Suit Rights Notification Procedures
7. Proposed Compliance Manual §80, Compliance Review

#### Closed

1. Litigation Authorization: General Counsel Recommendations
2. Options Paper on Enforcement of an ORA Decision

**Note.**—Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission Meetings in the Federal Register, the Commission also provides a recorded announcement a full week in advance on future Commission sessions. Please telephone (202) 634-6748 at all times for information on these meetings).

#### CONTACT PERSON FOR MORE

**INFORMATION:** Cynthia C. Matthews, Executive Officer, Executive Secretariat at (202) 834-8748.

Dated: April 24, 1985.  
Cynthia C. Matthews,  
Executive Officer.  
This Notice Issued April 24, 1985.

[FR Doc. 85-10291 Filed 4-24-85; 8:45 am]

BILLING CODE 6750-06-M

### 2

#### FEDERAL ENERGY REGULATORY COMMISSION

**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** 49 FR 15669, April 19, 1985.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:** 10:00 a.m., April 24, 1985.

**CHANGE IN THE MEETING:** The following Docket Numbers and Companies have been added:

Item No., Docket No., and Company

P-2 (B)  
Project No. 7563-000, South Fork II, Inc.  
(Week Falls)

RP-2  
TA85-1-37-000 and TA85-2-37-000,  
Northwest Pipeline Corporation

RP-10  
RP85-58-000, El Paso Natural Gas  
Company

Kenneth F. Plumb,  
Secretary.

[FR Doc. 85-10227 Filed 4-24-85; 8:45 am]

BILLING CODE 6717-02-M

### 3

#### FEDERAL MARITIME COMMISSION

**TIME AND DATE:** 9:00 a.m., May 1, 1985.

**PLACE:** Hearing Room One, 1100 L Street NW., Washington, D.C. 20573.

**STATUS:** Parts of the meeting open to the public. The rest of the meeting closed to the public.

#### MATTERS TO BE CONSIDERED:

##### Portions Open to the Public

1. Agreement No. 207-010737: Italia/Transatlantica Joint Service Agreement.
2. Agreement No. 202-009546-027: Modification of the United States Atlantic Ports/Eastern Mediterranean and North African Freight Conference to expand the geographic scope and appropriately alter the conference name; add U.S. microbridge authority; enlarge the independent action notice period; and, alter provisions dealing with rates on government-compelled agricultural cargoes.

#### Portions Closed to the Public

1. Activities of Marcella Shipping Company Ltd.
2. Activities of Cari-Cargo International, Inc./Jorge Villena.
3. Petition of Concorde/Nopal Line for Issuance of Regulations To Adjust and Meet Conditions Unfavorable to Shipping in the Foreign Trade of the United States—Consideration of the Record.
4. Docket No. 84-34: Shipping Conditions in the United States/Argentina Trade—Consideration of the Record.
5. Agreement No. 202-010689: Actions of the Transpacific Westbound Rate Agreement.

#### CONTACT PERSON FOR MORE

**INFORMATION:** Bruce A. Dombrowski, Acting Secretary, (202) 523-5725.

Bruce A. Dombrowski,

Acting Secretary.

[FR Doc. 85-9760 Filed 4-24-85; 8:45 am]

BILLING CODE 6730-01-M

### 4

**TIME AND DATE:** 10:00 a.m., Wednesday, May 1, 1985.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC. 20551.

**STATUS:** Closed.

#### MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

#### CONTACT PERSON FOR MORE

**INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 23, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-10202 Filed 4-24-85; 8:45 am]

BILLING CODE 6210-01-M

### 5

#### LEGAL SERVICES CORPORATION BOARD OF DIRECTORS

Cancellation of Board Meeting



**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** Published April 16, 1985, 50 FR 15035.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:** 9:00 a.m., Friday, April 26, 1985.

**CHANGE IN MEETING:** The Meeting of the Board of Directors of the Legal Services Corporation scheduled for April 26, 1985, at 9:00 a.m. is cancelled.

**EXPLANATION OF CHANGE:** The Chairman of the Operations and Regulations Committee, due to scheduling problems, will be unable to present any recommendations to the Board on April 26, 1985. It is the sense of the Chairman of the Audit and Appropriations Committee that the Committee will be unable to make any recommendations for Board action by April 26, 1985. Because action on recommendations of the two Committees constitute the major action items on the agenda of the previously announced meeting, the meeting is cancelled since there will be no items before the Board upon which action will be required.

**CONTACT PERSON FOR MORE INFORMATION:** Dennis Daugherty, Executive Office, (202) 272-4040.

Date Issued: April 24, 1985.

Dennis Daugherty,  
Acting Secretary.

[FR Doc. 85-10241 Filed 4-24-85; 8:45 am]

BILLING CODE 6820-35-M

## 6

# NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES, INSTITUTE OF MUSEUM SERVICES

**SUMMARY:** This notice sets forth the agenda of a forthcoming meeting of the National Museum Services Board. This notice also describes the functions of the Board. Notice of this meeting is required under the Government in the Sunshine Act (Pub. L. No. 94-409) and regulations of the Institute of Museum Services, 45 CFR 1180.84.

**TIME AND DATE:** 10:00 a.m. May 31-June 1, 1985.

**STATUS:** Open and closed.

**ADDRESS:** Room M07, 1100 Pennsylvania Avenue, NW., Washington, D.C. 20506.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robin N. Rapp, Executive Assistant to the National Museum Services Board, Room 510, 1100 Pennsylvania Avenue, NW., Washington, D.C. 20506 (202) 786-0536.

## SUPPLEMENTARY INFORMATION:

The National Museum Services Board is established under the Museum Services Act which is Title II of the Arts, Humanities, and Cultural Affairs Act of 1976, Pub. L. 94-402.

The Board has the responsibility for the general policies with respect to the powers, duties, and authorities vested in the Institute under this Title. Grants are awarded by the Institute of Museum Services after review by the Board.

The meeting of May 31-June 1 will be open to the public from 10:30 a.m. through discussion of agenda item number 7. The meeting will be closed to the public for a review of agenda item 8 pursuant to paragraphs 6, 9 (B), and other relevant provisions of subsection (c) of section 552 of Title 5, United States Code because the Board will consider information that may disclose: Information of a personal nature that disclosure of which would constitute a clear unwarranted invasion of privacy; and information the disclosure of which might significantly frustrate implementation of proposed agency action related to the award process.

The agenda for the meeting will be as follows:

- I. Approval of the Minutes of March 15, 1985 Meeting
- II. Director's Report
- III. Regulatory and Legislative Update
- IV. Conservation Program Update
- V. Other Business
- VI. Proposed Changes to GOS Application and Regulations
- VII. Review of 1985 GOS Applications Processing
- VIII. Review of 1985 GOS Applications

Dated: April 22, 1985.

Susan E. Phillips,  
Director.

[FR Doc. 85-10275 Filed 4-24-85; 8:45 am]

BILLING CODE 7030-01-M

## 7

# POSTAL SERVICE BOARD OF GOVERNORS

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 CFR 7.5) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice that it intends to hold meetings at 1:00 p.m. on Monday, May 6, 1985, in Washington, D.C., and at 8:30 a.m. on Tuesday, May 7, 1985, in the Benjamin Franklin Room, U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., Washington, D.C. As indicated in the following paragraph, the May 6 meeting is closed to public observation. The May 7 meeting is open to the public. The Board expects to discuss the matters stated in the agenda which is set forth below. Requests for information about the meetings should be addressed to the Secretary of the Board, David F. Harris, at (202) 245-3734.

At its meeting on April 1, 1985, the Board voted in accordance with the provisions of the Government in the Sunshine Act to close to public observation its meeting scheduled for May 6. (See 50 FR 13914, April 8, 1985.)

The meeting will involve a discussion of personnel matters.

## Agenda

### Monday Session

May 6, 1985—1:00 p.m. (Closed)

1. Discussion of Personnel Matters.

### Tuesday Session

May 7, 1985—8:30 a.m. (Open)

1. Minutes of the Previous Meeting, April 1-2, 1985.
2. Remarks of the Postmaster General. (In keeping with its consistent practice, the Board's agenda provides this opportunity for the Postmaster General to inform the Members of miscellaneous current developments concerning the Postal Service. Nothing that requires a decision by the Board is brought up under this item.)
3. Quarterly Report on Financial Performance. (Mr. Cummings, Senior Assistant Postmaster General, Finance Group, will present the quarterly summary on financial performance.)
4. Quarterly Report on Service Performance. (Mr. Jellison, Senior Assistant Postmaster General, Operations Group, will present the quarterly summary on service performance.)
5. Consideration of a Tentative Agenda for the June 3-4, 1985, meeting of the Board in Washington, DC.

David F. Harris,  
Secretary.

[FR Doc. 85-10265 Filed 4-24-85; 8:45 am]

BILLING CODE 7710-12-M

## 8

# SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of April 29, 1985.

A closed meeting will be held on Tuesday, April 30, 1985, at 10:00 a.m. Open meetings will be held on Tuesday, April 30, 1985, at 1:30 p.m. and on Thursday, May 2, 1985, at 2:00 p.m., in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10).



Commissioner Marinaccio, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, April 30, 1985, at 10:00 a.m., will be:

- Formal orders of investigation.
- Settlement of injunctive action.
- Institution of administrative proceeding of an enforcement nature.
- Institution of injunctive actions.
- Litigation matter.

The subject matter of the open meeting scheduled for Tuesday, April 30, 1985, at 1:30 p.m., will be.

The Commission will meet the representatives of the Financial Executive Institute's Committee on Corporate Reporting to discuss matters of mutual interest including the accounting and reporting requirements under the Securities Act and the Securities Exchange Act as well as ongoing projects involving the appropriate accounting for pensions, income taxes and inflation. For further information, please contact Robert Burns at (202) 272-2130.

The subject matter of the open meeting scheduled for Thursday, May 2, 1985, at 2:00 p.m., will be.

The Commission will meet with the Investment Dealers Association of Canada to discuss issues of mutual interest relating to

the internationalization of the world securities markets. For further information, please contact Andrew E. Feldman at (202) 272-2399.

At times changes in commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: John Stempel at (202) 272-2405.

John Wheeler,

Secretary.

April 22, 1984.

[FR Doc. 85-10201 Filed 4-24-85; 8:45 am]

BILLING CODE 8010-01-M



THE HISTORY OF THE  
CITY OF BOSTON  
FROM 1630 TO 1880  
BY  
JOHN B. HENNINGSON  
BOSTON: PUBLISHED BY  
J. B. HENNINGSON, 100 NASSAU ST.  
N. Y. 1880



# Testigat Federal

Friday  
April 26, 1985

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## Part II

## Department of Labor

Employment Standards Administration,  
Wage and Hour Division

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Minimum Wages for Federal and  
Federally Assisted Construction; General  
Wage Determination Decisions



## DEPARTMENT OF LABOR

Employment Standards  
Administration, Wage and Hour  
DivisionMinimum Wages for Federal and  
Federally Assisted Construction;  
General Wage Determination  
Decisions; Notice

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 5.1 (including the statutes listed at 36 FR 306 (1970) following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations. Procedure for Predetermination of Wage Rates, 48 FR 19533 (1983) and of Secretary of Labor's Orders 9-83, 48 FR 35736 (1983), and 6-84, 49 FR 32473 (1984). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas  
Decisions to General Wage  
Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 5.1 (including the statutes listed at 36 FR 306 (1970) following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations. Procedure for Predetermination of Wage Rates, 48 FR 19533 (1983) and of Secretary of Labor's Orders 6-84, 49 FR 32473 (1984). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards

Administration, Wage and Hour Division, Office of Program Operations, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage  
Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

California: CA84-5007	May 18, 1984
Colorado: CO85-5021	Apr. 12, 1985
Hawaii: HI84-5019	July 20, 1984
Illinois: IL84-4006	Mar. 23, 1984
Iowa:	
IA84-4043	June 15, 1984
IA83-4022	Mar. 11, 1983
Nevada:	
NV84-5012	May 18, 1984
NV83-5121	Sept. 23, 1983
NV84-5014	June 8, 1984
NV84-5017	June 29, 1984
New York:	
NY84-3036	Sept. 14, 1984
Ohio:	
OH83-5123	Dec. 2, 1983
OH83-5124	Do.
OH83-5125	Dec. 23, 1983
OH83-5127	Do.
Oklahoma:	
OK84-4049	Sept. 7, 1984
OK84-4050	Do.
Texas:	
TX84-4045	Aug. 10, 1984
TX85-4003	Feb. 22, 1985
Wisconsin:	
WI83-2041	May 13, 1983
WI84-5010	June 22, 1984

Cancellation of General Wage  
Determination Decision

General Wage Decision Number TX84-4046, Bexar County, Texas is cancelled. Agencies with construction projects pending to which the cancelled decision would have been applicable should utilize the project determination procedure by submitting form SF-308. See Regulations Part 1, 29 CFR, section 1.5. Contracts for which bids have been opened shall not be affected by this notice. Also consistent with 29 CFR, 1.6(c)(3)(i), the incorporation of the cancelled decision in contract specifications, the opening of bids for which is within ten (10) days of the notice, need not be affected.

Supersedeas Decisions to General Wage  
Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the **Federal Register** are listed with each State. Supersedeas decision numbers are in parentheses following the number of the decisions being superseded.

Florida: FL83-1084 (FL85-3024) Oct. 28, 1983  
Signed at Washington, D.C., this 19th day of April 1985.

James L. Valin,  
Assistant Administrator.

BILLING CODE 4510-27-M



DECISION NO. CA84-5007 - MOD. #10	Basic County Rates	Fringe Benefits
Changes: Drywall Installer/Lathers Imperial, Inyo, Kern, etc - Counties, California		
ADD: Drywall Installer/Lathers/ Lathers: Inyo, Kern and Mono Counties:	\$16.66	\$5.05

DECISION NUMBER HIS4-5019 - MOD. #3 (9 FR 19515 - July 20, 1984) Statewide, Hawaii	Basic County Rates	Fringe Benefits
Changes: Asbestos Workers Electricians/ Electricians	\$15.96 16.50	\$8.40 3.65 + 30.61
Technicians	17.00	3.65 + 30.61
Cable Splicers	18.15	3.65 + 30.61
Residential Repair	15.66	3.65 + 30.61
Line Constructors/ Electricians; Linemen	16.50	3.65 + 30.61
Technicians	17.00	3.65 + 30.61
Heavy Equipment Operators	14.85	3.65 + 30.61
Groundsmen; Truck Drivers	12.38	3.65 + 30.61
Cable Splicers	18.15	3.65 + 30.61
Painters/ Brush	16.65	7.24
Tapers	16.90	7.24
Spray; Sandblaster	17.15	7.24
Plumbers; Pipefitters; & Steamfitters	17.00	8.32
Sprinkler Fitters	17.37	3.98

DECISION NO. CO85-5021 - MOD. #1	Basic County Rates	Fringe Benefits
Changes: Painters: Area 1: Brush Spray, Swing Stage		
Area 2: Brush Spray, Swing Stage		
Area 3: Brush Spray, Swing Stage		
Truck Drivers Zone 1 and 2 Fringe Benefits Only	\$15.06	\$3.19
Heading for Power Equip- ment Operators and Truck Drivers Zone 2 from "Fringe Benefits" to "Basic Hourly Rate"	16.12	2.31-34
Line Construction: Journeyman Lineman, Gas Fitters, Welder Line Equipment Operator Line Truck Driver Groundman	16.88	2.00-34
	13.33	2.00-34
	10.28	2.00-34

## CHANGE: (COND'T)

Painters:  
Area 1:  
Brush  
Spray, Swing Stage

Area 2:  
Brush  
Spray, Swing Stage

Area 3:  
Brush  
Spray, Swing Stage

Truck Drivers Zone 1 and 2  
Fringe Benefits Only

Heading for Power Equip-  
ment Operators and Truck  
Drivers Zone 2 from  
"Fringe Benefits" to  
"Basic Hourly  
Rate"

\*Counties Zone Definitions  
Power Equipment Operators

## Counties entirely within Zone 1:

Alameda  
Archuleta  
Bent  
Boulder  
Chaffee  
Clear Creek  
Conejos  
Costilla  
Crowley

Custer  
Delta  
Denver  
Douglas  
El Paso  
Fremont  
Garfield  
Gilpin

Huerfano  
Jefferson  
La Plata  
Larimer  
Logan  
Mesa  
Montezuma  
Morgan

Otero  
Phillips  
Prowers  
Pueblo  
Rio Grande  
Sedgwick  
Teller  
Weld

## Counties entirely within Zone 2:

Baca  
Cheyenne  
Dolores  
Grand  
Gunnison  
Hinsdale

Jackson  
Kiowa  
Kit Carson  
Lake  
Lincoln  
Mineral

Moffat  
Ouray  
Park  
Pitkin  
Rio Blanco  
Saguache  
San Juan  
San Miguel  
Summit  
Yuma



DECISION NO. 114-4008 (Cont'd)	Basic Hourly Rate	Fringe Benefits
<b>POWER EQUIPMENT OPERATORS:</b> Master, Mechanic Group 1 Group 2 Group 3 Group 4 Group 5 Group 6 a b c d	19.03 18.57 15.14 14.49 14.39 14.14 20.72 21.02 16.14 16.74	2.73 2.73 2.73 2.73 2.73 2.73 2.73 2.73 2.73 2.73
<b>DECISION #1844-4043-MOD.#7 (48 FR 14858-June 15, 1981)</b> Black Hawk, Cerro Gordo, Clinton, Des Moines, Dubuque, Johnson, Linn, and Polk Counties, Iowa <b>CRANES:</b> Bricklayers & Stonemasons: Scaffolding Glaziers: Towers 1, 2, & 3 Electricians Zone 2	\$11.25 13.80 14.51	\$ .57 2.57 + 1.40 + 3.75%
<b>DECISION #1845-4022-MOD.#4 (48 FR 10577-Mar. 11, 1981)</b> Statewide Iowa (except Cerro Gordo, Scott, and Webster Counties, Iowa) <b>OMIT:</b> Omit the Black Hawk County jurisdiction and wage rates from heavy construction projects.		

DECISION NO.	DATE	Basic Hourly Rate	Fringe Benefits
749 FR 21261-May 18, 1984)		\$14.65	\$5.34
Nevada Test Site including Tonopah Test Range in Clark, Lincoln and Nye Counties Nevada			
CHANGE:			
Roofers			
749 FR 21261-June 8, 1984)			
Statewide (does not include the Nevada Test Site and Tonopah Test Range, or Building construction in Churchill, Lyon and Mineral Counties, or highway construction in Douglas County), Nevada			
CHANGE:			
Cement Masons:			
Area 2:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			
Area 3:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			
NOO: ROOFER - Area 1			
749 FR 26874-June 29, 1984)			
Washoe County, Nevada			
CHANGE:			
Cement Masons:			
Lake Tahoe Area:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			
Remainder of Washoe County:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			
749 FR 26874-June 29, 1984)			
Washoe County, Nevada			
CHANGE:			
Cement Masons:			
Lake Tahoe Area:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			
Remainder of Washoe County:			
Cement Masons			
Mastic, Magnesite and all Composition Masons			
Troweling Machine:			
Grinder Operator and Kelly Float			

DECISIONS NO. NV84-5014 -  
WFOO #11  
7/19/84  
Statewide (does not include the Nevada Test Site and Toiyah Test Range, or Building construction in Churchill, Lyon and Mineral Counties, or highway construction in Douglas County), Nevada

Charge:  
Cement Masons:  
Area 2:  
Cement Masons  
Mastic, Magnesite and  
all Composition Masons  
Troweling Machine;  
Grinder Operator and  
Kelly Float  
Area 3:  
Cement Masons  
Mastic, Magnesite and  
all Composition Masons  
Troweling Machine;  
Grinder Operator and  
Kelly Float  
QOO: ASSET - Area 1

DECISION NO. NV84-5017-  
WFOO #15  
7/19/84  
Statewide (does not include the Nevada Test Site and Toiyah Test Range, or Building construction in Churchill, Lyon and Mineral Counties, or highway construction in Douglas County), Nevada

Charge:  
Cement Masons:  
Lake Tahoe Area:  
Cement Masons  
Mastic, Magnesite and  
all Composition  
Masons  
Troweling Machine;  
Grinder Operator and  
Kelly Float  
Remainder of Washoe County:  
Cement Masons  
Mastic, Magnesite and  
all Composition Masons  
Troweling Machine;  
Grinder Operator and Kelly Float



DECISION NUMBER	DATE	NO.	Basic Hourly Rate	Fringe Benefits
DECISION NUMBER 0853-5122 - MOD. #3 (48 FR 54419 - December 2, 1983)	1983	48	\$17.67	53.36
Manufacturing & Trumbull Counties, Ohio				
Change:				
Sprinkler Fitters				
Area 1			\$17.27	53.55
Area 2			16.20	3.49
Area 3			17.51	4.68
Area 4			17.67	3.38
Area 5				
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OBJECTS FROM NO. F. 85-3024

## SUPRESEDEAS DECISION

STATE: FLORIDA  
COUNTIES: \*SEE BELOW  
DECISION NUMBER: FLS-3024  
DATE: Date of Publication  
FAS-1894 dated October 26, 1983 at 8 PM 4993.  
Ordinance Decision No.: FAS-1894 dated October 26, 1983 at 8 PM 4993.  
DESCRIPTION OF WORK: BUILDING CONSTRUCTION PROJECTS (Does not include single family homes or apartments of less than 4 units)  
HEAVY CONSTRUCTION & HIGHWAY CONSTRUCTION PROJECTS.  
Case: Cavalier Air Force Station, Patrick Air Force Base, Brevard County, Florida.  
Cavalier Air Force Station, Patrick Air Force Base, Volusia County, Florida.  
Cavalier Air Force Station, Patrick Air Force Base, Volusia County, Florida.

Motor City • 521.1800

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# Register Federal

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Friday  
April 26, 1985

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## Part III

### Department of Housing and Urban Development

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Office of the Assistant Secretary for  
Housing—Federal Housing Commissioner

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24 CFR Part 888

Section 8—Fair Market Rents for New  
Construction and Substantial  
Rehabilitation—All Market Areas; Interim  
Rule



DEPARTMENT OF HOUSING AND  
URBAN DEVELOPMENTOffice of the Assistant Secretary for  
Housing—Federal Housing  
Commissioner

24 CFR Part 888

[Docket No. R-85-1224; FR-2079]

Section 8—Fair Market Rents for New  
Construction and Substantial  
Rehabilitation—All Market AreasAGENCY: Office of the Assistant  
Secretary for Housing—Federal Housing  
Commissioner, HUD.

ACTION: Interim rule.

**SUMMARY:** This rule amends the Section 8 Fair Market Rents applicable to New Construction and Substantial Rehabilitation for all market areas in compliance with the requirements of Section 8(c)(1) of the U.S. Housing Act of 1937. Revised Section 8 Fair Market Rents (FMRs) must be published at least annually in the *Federal Register*. HUD published the last annual revision of the FMRs for Section 8 New Construction and Substantial Rehabilitation on February 8, 1984 at 49 FR 4892.

The amended Fair Market Rents reflect the changes which have occurred in the general level of market rents for recently completed or newly constructed dwelling units of modest design within each market area since their last Annual or Special (Interim) Revision.

**DATES:** Effective Date: After the comment deadline date set forth below, notice of the effective date of this rule will be published in the *Federal Register*.

Comments must be received by: May 28, 1985.

**ADDRESS:** Comments should be sent to the Rules Docket Clerk, Room 10276, Office of the General Counsel, Department of Housing and Urban Development, 451-7th Street SW., Washington, DC 20410-0500. Each person submitting a comment should include his/her name and address and refer to the docket number and title shown in the heading of this rule and give reasons for any recommendation. A copy of each comment submitted will be available for public inspection in the Office of the Rules Docket Clerk during regular business hours. In order to expedite consideration of comments, a copy of each comment should also be sent to the HUD Field Office having jurisdiction for the market area involved.

**FOR FURTHER INFORMATION CONTACT:** Edward M. Winiarski, Chief Appraiser, Valuation Branch, Technical Support Division, Office of Insured Multifamily Housing Development, 451-7th Street SW., Washington, DC 20410-8000, (202) 426-7624. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Fair Market Rents are based primarily on the level of rentals paid for recently completed or newly constructed dwelling units of modest design within each market area, as determined by HUD Field Office staff. They are estimates of rentals that prospective tenants who are not receiving Federal rental subsidies would be willing to pay for recently completed or newly constructed dwelling units of modest design.

The revised Fair Market Rents in Schedule A of Part 888 as adopted by this Interim Rule, have been trended ahead to October 1, 1986, to allow for the period of construction or rehabilitation of the projects involved.

This interim rule includes Fair Market Rents for 0, 1, 2, 3, and 4 or more bedroom units in five structural categories (detached, semi-detached/row, walkup, elevator 2-4 story, and 5 plus story). Construction or rehabilitation of elevator projects for families with children is legally prohibited unless there is no practical alternative. Fair Market Rents for family units in elevator structures have been listed in these schedules for appropriate market areas. However, the determination that there is "no practical alternative" must be made on a project by project basis.

In addition, regulations provide that high-rise elevator projects for the *elderly* may be approved *only* if HUD determines that high-rise construction is appropriate after taking into account land costs, safety and security factors.

Proposals involving combinations of structural types and unit sizes for which Fair Market Rents have not yet been published may not be approved until the applicable Fair Market Rents are published and become effective.

A discussion of the applicability of a particular schedule of Fair Market Rents, where the rents are revised downward, follows:

1. In the State Agency Program (under 24 CFR Part 883) the Fair Market Rents in effect on the date the "Application for Assignment of Portion of Set-Aside to Specific Project" is submitted to HUD shall apply, except in those instances

where a Proposal or Preliminary Proposal is submitted before the Application. In the latter cases, the Fair Market Rents that are in effect on the date of the submission of the Proposal or Preliminary Proposal shall apply.

2. For New Construction and Substantial Rehabilitation Projects (Under 24 CFR Parts 880, 881, and 885) which are not subject to a Notice of Fund Availability (NOFA) nor to a deadline in a NOFA, the Fair Market Rents in effect on the date that the Preliminary Proposal or Section 202 Application for Fund Reservation is submitted shall apply.

3. For New Construction and Substantial Rehabilitation Projects which are subject to deadlines stated in NOFAs, the Fair Market Rents stated in the NOFA shall apply.

For all projects where the Fair Market Rents are revised upward after the date of the processing stage specified above, the revised Fair Market Rents shall apply to all subsequent processing in reviewing Contract Rents.

Interested persons will have a 30-day comment period after publication of this Interim Rule in which to submit comments on the revised Fair Market Rents contained in Schedule A. If evaluation of comments submitted during that period indicates a need to change any of the Fair Market Rents in Schedule A, such Fair Market Rents will be withdrawn or revised, as appropriate.

In addition, interested persons may submit comments or other information (with adequate documentation) on Fair Market Rents at any time, even after expiration of the 30-day public comment period provided in this rule. Any data submitted will be considered in initiating interim revisions to the Fair Market Rent schedules. In order to expedite consideration of your submission, please send a copy to the HUD Field Office having jurisdiction for the market area involved.

HUD regulations in 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, contain categorical exclusions from their requirements for the actions, activities and programs specified in § 50.20. Since the amendments made by this rule are within the exclusion set forth in § 50.20(1), no environmental assessment is required for this rule, and no environmental finding has been prepared.

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291 on Federal Regulation. Analysis of the rule



indicates that it does not (1) have an annual effect on the economy of \$100 million or more; (2) cause a major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule is not listed in the Department's Semiannual Agenda of Regulations published on October 22, 1984 (49 FR 41684), pursuant to Executive Order 12291 and the Regulatory Flexibility Act.

Pursuant to the provisions of 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. Although this rule will have an effect on developers and owners of Section 8 projects, some of whom may constitute small entities, it is not expected that the economic impact on them will be significant.

The Catalog of Federal Domestic Assistance Program number and title for the activities covered by this rule is 14.156, Lower Income Housing Assistance Program (Section 8).

#### List of Subjects in 24 CFR Part 888

Rent subsidies.

Accordingly, Schedule A of 24 CFR Part 888 is revised to read as set forth below.

**Authority:** Section 8(c)(1) of the U.S. Housing Act of 1937, 42 U.S.C. 1437f(c)(1); Section 7(d), Department of HUD Act, 42 U.S.C. 3535(d).

Dated: March 19, 1985.

**Shirley McVay Wiseman,**

*General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.*

#### **Schedule A—Fair Market Rents for New Construction and Substantial Rehabilitation (Including Housing Finance and Development Agencies Program)**

These Fair Market Rents have been trended ahead to October 1, 1986, to update the current Fair Market Rent schedules which these revised schedules will replace.

**Note.**—The Fair Market Rents for (1) dwelling units designed for the elderly or handicapped are those for appropriate size, units, not to exceed 2 bedrooms for the elderly, multiplied by 1.05; (2) congregate housing dwelling units are the same as for noncongregate units; (3) single room occupancy dwelling units (applicable only for Substantial Rehabilitation projects) are 75 percent of those for zero bedroom units of the same structural type; (4) living units in a group home (each composed of a bedroom plus a proportionate part of common living space which is ordinarily included in a living unit) are those for zero bedroom or one bedroom units of the walkup structural type (or, if the group home contains an elevator, of the elevator 2-4 story structural type). In group homes, one bedroom Fair Market Rents may be applied only when the bedroom space plus the proportionate part of the common space is at least 450 square feet; (5) manufactured homes (unit and space) shall be 95 percent of the rents for detached units of the appropriate bedroom size (except that where a manufactured home Fair Market Rent is given on the schedule for the area, the amount on the schedule shall be the Fair Market Rent); (6) manufactured home spaces in newly-constructed or substantially rehabilitated manufactured home parks shall be the Fair Market Rents for spaces published for the Existing Housing Program under Schedule D, multiplied by 1.25.

All rents computed in accordance with this note shall be rounded down to the nearest whole dollar.

Similarly, all Fair Market Rents increased by up to 10 percent with the approval of the HUD Field Office Manager, or by up to 20

percent with the approval of the HUD Assistant Secretary for Housing should have the result rounded down to the nearest whole dollar.

The decision relative to the selection of appropriate FMRs for use in project processing must be based upon an entire schedule rather than selectively choosing the highest unit rents from both the current effective FMR schedule and a prior published one for that market area.

Since the 1984 FMRs were published, the market areas for the State of New Mexico have been consolidated into five areas. For the convenience of the user, last year's market areas are listed below, under their new market area designations:

*Albuquerque*

*Albuquerque  
Isleta*

*Clovis*

*Alamogordo*

*Artesia*

*Carlsbad*

*Clovis*

*Hobbs*

*Las Cruces*

*Mescalero*

*Socorro*

*Truth or Consequences*

*Sante Fe*

*Fort Sumner*

*Las Vegas*

*Pojoaque*

*Raton*

*Santa Fe*

*Silver City*

*Dulce*

*Farmington*

*Gallup*

*Jemez*

*Laguna*

*Los Alamos*

*Ruidoso*

*Silver City*

*Tierra Amari*

*Taos*

*Penasco*

*Taos*

**BILLING CODE 4210-27-M**



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 1

## BOSTON, MASSACHUSETTS AREA OFFICE

STRUCTURE TYPE	MARKET: BOSTON NUMBER OF BEDROOMS					MARKET: WORCESTER NUMBER OF BEDROOMS					MARKET: FALL RIVER NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			742	952	1035			689	880	959			711	835	870
SEMI-DETACHED/ROW		625	733	866	959		554	681	795	911		551	697	844	855
WALKUP	539	609	730	805	913	495	527	661	749	861	513	532	658	753	790
ELEVATOR 2-4 STY	559	679	784	1018	1162	505	580	695			531	551	672		
ELEVATOR 5+ STY	559	679	784	1096	1209	530	611	731			533	580	702		
MANUFACTURED HOME															
EFFECTIVE DATE						100184					100184				
TRENDING DATE						100186					100186				

## HARTFORD, CONNECTICUT AREA OFFICE

STRUCTURE TYPE	MARKET: HARTFORD NUMBER OF BEDROOMS					MARKET: NEW HAVEN NUMBER OF BEDROOMS					MARKET: NEW LONDON NUMBER OF BEDROOMS					MARKET: NEW MILFORD NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			657	731	752			638	721	770			635	709	740			588	656	673
SEMI-DETACHED/ROW		543	626	709	731		526	592	697	749		471	603	673	717		510	588	656	673
WALKUP	451	523	595	671	693	450	503	570	649	671	421	452	594	667	691	424	492	559	630	651
ELEVATOR 2-4 STY	457	531	599			462	518	606			424	466	616			429	499	563		
ELEVATOR 5+ STY	472	577	665			479	571	675			449	515	635			443	542	625		
MANUFACTURED HOME																				
EFFECTIVE DATE						100184					100184					100184				
TRENDING DATE						100186					100186					100186				

STRUCTURE TYPE	MARKET: WINDHAM NUMBER OF BEDROOMS					MARKET: BRIDGEPORT NUMBER OF BEDROOMS					MARKET: RIDGEFIELD NUMBER OF BEDROOMS					MARKET: NORWICH NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			545	603	626			637	680	710			739	792	820			588	656	673
SEMI-DETACHED/ROW		465	520	582	606		527	607	658	688		611	704	770	798		519	588	656	673
WALKUP	381	443	497	551	567	437	506	574	638	661	506	589	669	749	771	432	502	570	631	650
ELEVATOR 2-4 STY	403	461	507			443	530	581			515	598	676			438	509	575		
ELEVATOR 5+ STY	420	489	558			461	560	645	*		531	649	747			454	545	635		
MANUFACTURED HOME																				
EFFECTIVE DATE						100184					100184					100184				
TRENDING DATE						100186					100186					100186				

## MANCHESTER, NEW HAMPSHIRE SERVICE OFFICE

STRUCTURE TYPE	MARKET: MAINE STATEWIDE NUMBER OF BEDROOMS					MARKET: VERMONT STATE NUMBER OF BEDROOMS					MARKET: NEW HAMPSHIRE ST. NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED		540	609	695	806		560	655	738	840		538	602	694	806
SEMI-DETACHED/ROW	425	499	569	655	759	466	523	616	691	780	457	509	573	657	762
WALKUP	381	463	542	615	694	417	488	580	654	721	403	453	520	592	673
ELEVATOR 2-4 STY	426	509	641			473	540	640			426	516	594		
ELEVATOR 5+ STY	473	568	713			525	599	711			473	572	660		
MANUFACTURED HOME															
EFFECTIVE DATE						100184					100184				
TRENDING DATE						100186					100186				

## PROVIDENCE, RHODE ISLAND SERVICE OFFICE

STRUCTURE TYPE	MARKET: PROVIDENCE NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			661	769	861
SEMI-DETACHED/ROW		482	561	624	672
WALKUP	361	470	542	610	655
ELEVATOR 2-4 STY	361	485	630		
ELEVATOR 5+ STY	363	490	636		
MANUFACTURED HOME					
EFFECTIVE DATE					100184
TRENDING DATE					100186



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 2

## BUFFALO, NEW YORK AREA OFFICE

STRUCTURE TYPE	MARKET: BUFFALO NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			550	622	701
SEMI-DETACHED/ROW		414	483	567	656
WALKUP	315	372	448	526	560
ELEVATOR 2-4 STY	413	454	601		
ELEVATOR 5+ STY	449	490	637		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ELMIRA NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			533	618	684
SEMI-DETACHED/ROW		428	487	575	641
WALKUP	329	374	440	545	619
ELEVATOR 2-4 STY	395	473	557		
ELEVATOR 5+ STY	431	509	593		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: JAMESTOWN NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			543	610	684
SEMI-DETACHED/ROW		426	495	567	648
WALKUP	328	386	458	526	607
ELEVATOR 2-4 STY	401	473	581		
ELEVATOR 5+ STY	437	509	616		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ROCHESTER NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED				531	594 659
SEMI-DETACHED/ROW		418	488	567	641
WALKUP	323	375	451	511	576
ELEVATOR 2-4 STY	416	473	567		
ELEVATOR 5+ STY	452	509	606		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ALBANY NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			522	631	699
SEMI-DETACHED/ROW		385	461	560	620
WALKUP	328	374	439	517	585
ELEVATOR 2-4 STY	328	403	510		
ELEVATOR 5+ STY	357	441	550		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: PLATTSBURGH NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			531	626	691
SEMI-DETACHED/ROW		448	488	564	629
WALKUP	352	386	446	522	595
ELEVATOR 2-4 STY	392	464	564		
ELEVATOR 5+ STY	428	500	604		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: SYRACUSE NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			538	620	709
SEMI-DETACHED/ROW		398	472	568	638
WALKUP	310	371	453	517	595
ELEVATOR 2-4 STY	310	413	523		
ELEVATOR 5+ STY	349	450	562		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: BINGHAMTON NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED				519	626 692
SEMI-DETACHED/ROW		382	461	551	612
WALKUP	326	372	437	513	580
ELEVATOR 2-4 STY	326	405	515		
ELEVATOR 5+ STY	362	431	553		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

## NEW YORK, NEW YORK AREA OFFICE

STRUCTURE TYPE	MARKET: NEW YORK CITY NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED					
SEMI-DETACHED/ROW		628	865	1026	1253
WALKUP	564	589	802	960	1160
ELEVATOR 2-4 STY	602	774	828	1043	1225
ELEVATOR 5+ STY	785	956	1062	1348	1540
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: SUFFOLK NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			763	925	1031
SEMI-DETACHED/ROW		577	611	724	757 901
WALKUP	463	539	649	707	781
ELEVATOR 2-4 STY	595	699	851		
ELEVATOR 5+ STY	642	716	895		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: WESTCHESTER NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			866	1011	1107
SEMI-DETACHED/ROW		619	725	893	971
WALKUP	484	577	691	834	916
ELEVATOR 2-4 STY	599	685	841	984	
ELEVATOR 5+ STY	648	769	896		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ORANGE NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED				633	718 783
SEMI-DETACHED/ROW		451	572	681	745
WALKUP	324	447	542	636	703
ELEVATOR 2-4 STY	521	564	712		
ELEVATOR 5+ STY	560	640	782		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ROCKLAND NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			856	929	998
SEMI-DETACHED/ROW		613	764	889	965
WALKUP	455	577	721	837	927
ELEVATOR 2-4 STY	515	620	769		
ELEVATOR 5+ STY	563	670	810		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: NASSAU NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			914	1043	1146
SEMI-DETACHED/ROW		648	836	948	1051
WALKUP	501	624	757	869	963
ELEVATOR 2-4 STY	516	638	794		
ELEVATOR 5+ STY	522	733	846		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: PUTNAM NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			798	917	998
SEMI-DETACHED/ROW		537	684	821	896
WALKUP	434	509	587	734	852
ELEVATOR 2-4 STY	610	691	756		
ELEVATOR 5+ STY	653	751	834		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: POUGHKEEPSIE NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED				664	775 885
SEMI-DETACHED/ROW		485	577	664	729
WALKUP	387	462	575	616	684
ELEVATOR 2-4 STY	588	687	791		
ELEVATOR 5+ STY	615	713	854		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

## NEWARK, NEW JERSEY AREA OFFICE

STRUCTURE TYPE	MARKET: NEWARK NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			1055	1178	1253
SEMI-DETACHED/ROW		597	664	841	975 1061
WALKUP	525	587	752	873	956
ELEVATOR 2-4 STY	606	674	859	1000	1080
ELEVATOR 5+ STY	681	764	974	1141	1230
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: NORTH BERGEN NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			1048	1172	1246
SEMI-DETACHED/ROW		655	721	836	969 1054
WALKUP	581	642	745	866	949
ELEVATOR 2-4 STY	662	730	852	993	1073
ELEVATOR 5+ STY	737	820	968	1134	1223
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: FREEHOLD NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			970	1092	1168
SEMI-DETACHED/ROW		588	655	761	891 975
WALKUP	516	575	673	787	872
ELEVATOR 2-4 STY	595	663	773	915	994
ELEVATOR 5+ STY	670	753	889	1055	1146
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: CAMDEN NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED				925	1042 1114
SEMI-DETACHED/ROW		571	698	848	927
WALKUP	422	489	600	743	832
ELEVATOR 2-4 STY	543	609	741	889	967
ELEVATOR 5+ STY	620	699	870	1031	1117
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: ATLANTIC CITY NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			891	1008	1067
SEMI-DETACHED/ROW		598	680	811	893
WALKUP	475	532	602	721	797
ELEVATOR 2-4 STY	572	637	718	854	931
ELEVATOR 5+ STY	648	728	834	994	1082
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: BURLINGTON NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			925	1042	1114
SEMI-DETACHED/ROW		571	715	848	927
WALKUP	448	504	637	756	832
ELEVATOR 2-4 STY	544	609	753	889	967
ELEVATOR 5+ STY	620	699	870	1031	1117
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

STRUCTURE TYPE	MARKET: GLOUCESTER NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED			925	1042	1114
SEMI-DETACHED/ROW		571	705	848	927
WALKUP	432	502	606	753	832
ELEVATOR 2-4 STY	544	609	751	889	967
ELEVATOR 5+ STY	620	699	870	1031	1117
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: TRENTON				
NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+
		944	1061	1133
	642	733	866	945
489	557	656	774	851
510	682	772	907	985
808	728	888	1042	1128



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 2

## CARIBBEAN AREA OFFICE

	MARKET: SAN JUAN NUMBER OF BEDROOMS					MARKET: MAYAGUEZ NUMBER OF BEDROOMS					MARKET: PONCE NUMBER OF BEDROOMS					MARKET: ARECIBO NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			497	556	610			485	570	638			468	550	596			485	570	638
SEMI-DETACHED/ROW		431	477	541	561		430	475	561	637		431	468	550	596		430	475	561	637
WALKUP	328	391	461	504	554	321	381	428	487	560	321	381	425	487	560	321	381	428	487	560
ELEVATOR 2-4 STY																				
ELEVATOR 5+ STY	378	428	482	553	613	360	408	507	584	629	360	408	507	584	629	360	408	507	584	629
MANUFACTURED HOME																				
EFFECTIVE DATE					100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184
TRENDING DATE					100186	TRENDING DATE				100186	TRENDING DATE				100186	TRENDING DATE				100186

	MARKET: ST. CROIX NUMBER OF BEDROOMS					MARKET: ST. THOMAS NUMBER OF BEDROOMS					MARKET: OLD SAN JUAN NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			630	688	776			648	708	799			660	734	800
SEMI-DETACHED/ROW		417	471	553	621	707	485	485	569	639	726		552	606	682
WALKUP	338	392	477	536	598	355	410	500	559	627					
ELEVATOR 2-4 STY															
ELEVATOR 5+ STY															
MANUFACTURED HOME															
EFFECTIVE DATE					100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184
TRENDING DATE					100186	TRENDING DATE				100186	TRENDING DATE				100186

## REGION 3

## BALTIMORE, MARYLAND AREA OFFICE

STRUCTURE TYPE	MARKET: BALTIMORE NUMBER OF BEDROOMS					MARKET: HAGERSTOWN NUMBER OF BEDROOMS					MARKET: SALISBURY NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			685	773	908			626	696	802			582	642	753
SEMI-DETACHED/ROW		476	555	653	851		442	518	603	789		406	473	548	705
WALKUP	371	476	547	653	743	341	442	518	603	646	314	406	467	542	610
ELEVATOR 2-4 STY		401	501	594			366	460	523			325	445	487	
ELEVATOR 5+ STY		443	547	698			420	506	655			359	467	595	
MANUFACTURED HOME															
EFFECTIVE DATE					100184					100184					100184
TRENDING DATE					100186					100186					100186

## CHARLESTON, WEST VIRGINIA SERVICE OFFICE

STRUCTURE TYPE	MARKET: CHARLESTON NUMBER OF BEDROOMS					MARKET: BLUEFIELD NUMBER OF BEDROOMS					MARKET: HUNTINGTON NUMBER OF BEDROOMS					MARKET: PARKERSBURG NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			510	605	687			488	537	598			465	561	610			435	502	552
SEMI-DETACHED/ROW		377	488	605	687		361	460	502	540		371	455	530	585		346	409	474	522
WALKUP	296	377	473	484	546	307	361	408	456	501	238	371	455	505	553	279	346	399	450	496
ELEVATOR 2-4 STY		387	475	536			384	456	510			363	431	517			373	450	545	
ELEVATOR 5+ STY		398	482	542			391	462	518			368	437	522			382	456	552	
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: WHEELING NUMBER OF BEDROOMS					MARKET: MARTINSBURG NUMBER OF BEDROOMS					MARKET: FAIRMONT NUMBER OF BEDROOMS					MARKET: POINT PLEASANT NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			478	530	593			451	530	593			505	561	628			434	500	546
SEMI-DETACHED/ROW		346	446	516	569		340	431	505	569		422	476	537	602		324	405	471	519
WALKUP	267	341	435	478	521	268	340	431	478	540	314	392	458	505	556	235	320	398	443	493
ELEVATOR 2-4 STY		359	429	520			406	447	497			429	471	525			371	443	497	
ELEVATOR 5+ STY		364	435	525			413	452	503			436	477	531			376	452	504	
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 3

## PHILADELPHIA, PENNSYLVANIA AREA OFFICE

STRUCTURE TYPE	MARKET: PHILADELPHIA NUMBER OF BEDROOMS					MARKET: ALLENTOWN NUMBER OF BEDROOMS					MARKET: BELLEFONTE NUMBER OF BEDROOMS					MARKET: HARRISBURG NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		555	695	824	900		464	577	675	745		469	574	663	725		473	521	664	725
WALKUP	435	490	619	734	808	396	436	543	634	708	373	457	534	632	679	373	436	504	622	677
ELEVATOR 2-4 STY	529	592	732			467	493	578			406	474	589			424	492	543		
ELEVATOR 5+ STY	602	679	807			481	528	647			452	509	629			459	532	589		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: LANCASTER NUMBER OF BEDROOMS					MARKET: YORK NUMBER OF BEDROOMS					MARKET: READING NUMBER OF BEDROOMS					MARKET: SCRANTON NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		440	541	666	691		440	541	666	691		464	555	667	742		492	571	649	710
WALKUP	364	425	530	638	665	364	425	530	638	665	369	445	533	630	691	408	452	543	623	691
ELEVATOR 2-4 STY	441	510	663			441	510	663			422	498	577			463	537	606		
ELEVATOR 5+ STY	464	533	685			464	533	685			457	546	640			492	572	645		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: WELLSBORO NUMBER OF BEDROOMS																			
	-0-	-1-	-2-	-3-	-4+															
DETACHED																				
SEMI-DETACHED/ROW		469	574	663	725															
WALKUP	373	457	534	632	679															
ELEVATOR 2-4 STY	406	474	589																	
ELEVATOR 5+ STY	452	509	629																	
MANUFACTURED HOME																				
EFFECTIVE DATE					100184															
TRENDING DATE					100186															

## PITTSBURGH, PENNSYLVANIA AREA OFFICE

STRUCTURE TYPE	MARKET: PITTSBURGH NUMBER OF BEDROOMS					MARKET: ERIE NUMBER OF BEDROOMS					MARKET: ALTOONA NUMBER OF BEDROOMS					MARKET: JOHNSTOWN NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		572	667	744			516	649	760			518	620	727			515	612	730	
WALKUP	380	452	534	605	708	334	413	479	552	629	334	412	503	588	692	337	416	499	574	655
ELEVATOR 2-4 STY	412	483	546			404	454	536			400	469	519			401	468	524		
ELEVATOR 5+ STY	426	498	581			417	468	570			408	483	553			410	483	559		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

## RICHMOND, VIRGINIA AREA OFFICE

STRUCTURE TYPE	MARKET: NORTON NUMBER OF BEDROOMS					MARKET: HARRISONBURG NUMBER OF BEDROOMS					MARKET: NEWPORT NEWS NUMBER OF BEDROOMS					MARKET: NORFOLK NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		341	410	497	553		381	443	511	579		380	437	545	593		406	485	545	597
WALKUP	252	312	396	492	542	298	354	438	506	563	299	338	408	488	544	349	393	465	545	590
ELEVATOR 2-4 STY	284	344	428			330	386	471			331	369	439			381	425	497		
ELEVATOR 5+ STY	311	387	511			374	455	588			446	504	615			445	542	670		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: CHARLOTTESVILLE NUMBER OF BEDROOMS					MARKET: RICHMOND NUMBER OF BEDROOMS														
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+										
DETACHED																				
SEMI-DETACHED/ROW		426	503	595	632		393	456	533	579										
WALKUP	350	396	474	527	586	320	374	447	527	574										
ELEVATOR 2-4 STY	382	428	506			352	405	478												
ELEVATOR 5+ STY	422	511	643			398	484	625												
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184										
TRENDING DATE					100186					100186										



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 3

## WASHINGTON, D.C. AREA OFFICE

STRUCTURE TYPE	MARKET: WASHINGTON D.C. NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED					
SEMI-DETACHED/ROW	528	593	649	722	814
WALKUP	425	502	571	662	738
ELEVATOR 2-4 STY	459	553	713	782	
ELEVATOR 5+ STY	514	592	767	895	
MANUFACTURED HOME					
EFFECTIVE DATE					100184
TRENDED DATE					100186

## WILMINGTON, DELAWARE VALUATION AND ENDORSEMENT STATION

	MARKET: WILMINGTON, DEL					MARKET: DOVER, DEL				
	NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED			598	751	785			572	685	775
SEMI-DETACHED/ROW		436	533	640	702		400	482	593	646
WALKUP	361	418	493	573	614	353	381	433	516	557
ELEVATOR 2-4 STY	398	465	586			359	440	521		
ELEVATOR 5+ STY	423	539	598			381	486	578		
MANUFACTURED HOME										
	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184
	TRENDED DATE				100186	TRENDED DATE				100186

## REGION 4

## ATLANTA, GEORGIA AREA OFFICE

	MARKET: ATLANTA					MARKET: ALBANY					MARKET: AUGUSTA					MARKET: BRUNSWICK					
	NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	
DETACHED									450	524	552			420	493	535			456	536	570
SEMI-DETACHED/ROW	423	452	512	618	657	305	342	400	474	517	320	354	397	473	508	331	368	419	486	541	
WALKUP	412	437	500	605	643	295	333	389	463	499	310	339	383	458	497	320	357	414	475	519	
ELEVATOR 2-4 STY	438	464	526			320	358	414			337	366	409			347	383	441			
ELEVATOR 5+ STY	491	523	599			370	408	464			376	407	470			398	433	494			
MANUFACTURED HOME																					
	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	
	TRENDED DATE				100186	TRENDED DATE				100186	TRENDED DATE				100186	TRENDED DATE				100186	
	MARKET: COLUMBUS					MARKET: MACON					MARKET: ROME					MARKET: SAVANNAH					
	NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	
DETACHED									437	473	526			389	459	494			487	565	600
SEMI-DETACHED/ROW	309	344	385	493	530	332	364	413	451	506	257	296	338	407	453	341	376	453	513	560	
WALKUP	296	331	372	481	518	328	347	399	436	486	246	285	338	396	441	329	364	440	501	549	
ELEVATOR 2-4 STY	322	358	398			356	375	428			271	311	364			355	394	466			
ELEVATOR 5+ STY	375	413	450			407	436	496			323	362	416			405	445	517			
MANUFACTURED HOME																					
	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	EFFECTIVE DATE				100184	
	TRENDED DATE				100186	TRENDED DATE				100186	TRENDED DATE				100186	TRENDED DATE				100186	
	MARKET: VALDOSTA																				
	NUMBER OF BEDROOMS																				
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+																
DETACHED																					
SEMI-DETACHED/ROW	286	324	386	462	506																
WALKUP	275	306	376	439	495																
ELEVATOR 2-4 STY	300	338	408																		
ELEVATOR 5+ STY	350	389	460																		
MANUFACTURED HOME																					
	EFFECTIVE DATE				100184																
	TRENDED DATE				100186																



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 4

## BIRMINGHAM, ALABAMA AREA OFFICE

MARKET: BIRMINGHAM					MARKET: DOTHAN					MARKET: FLORENCE					MARKET: HUNTSVILLE				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			566	724 802	DETACHED			477	611 687	DETACHED			531	679 764	DETACHED			529	669 763
SEMI-DETACHED/ROW		351	417	504 540	SEMI-DETACHED/ROW		335	394	460 501	SEMI-DETACHED/ROW		334	397	483 522	SEMI-DETACHED/ROW		367	438	518 563
WALKUP	310	345	404	486 523	WALKUP	298	329	378	442 484	WALKUP	291	329	385	464 508	WALKUP	306	362	433	504 555
ELEVATOR 2-4 STY	321	363	428		ELEVATOR 2-4 STY	310	346	401		ELEVATOR 2-4 STY	303	341	406		ELEVATOR 2-4 STY	351	390	470	
ELEVATOR 5+ STY	333	381	453		ELEVATOR 5+ STY	322	346	426		ELEVATOR 5+ STY	316	353	418		ELEVATOR 5+ STY	362	408	494	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: MOBILE					MARKET: MONTGOMERY					MARKET: TUSCALOOSA				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			512	655 734	DETACHED			494	629 705	DETACHED			531	676 756
SEMI-DETACHED/ROW		355	423	506 543	SEMI-DETACHED/ROW		338	430	509 559	SEMI-DETACHED/ROW		361	419	521 556
WALKUP	303	343	412	487 530	WALKUP	309	333	412	504 552	WALKUP	320	356	406	503 541
ELEVATOR 2-4 STY	325	361	436		ELEVATOR 2-4 STY	321	351	435		ELEVATOR 2-4 STY	340	373	430	
ELEVATOR 5+ STY	336	378	459		ELEVATOR 5+ STY	332	368	460		ELEVATOR 5+ STY	353	391	454	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

## COLUMBIA, SOUTH CAROLINA AREA OFFICE

MARKET: GREENVILLE					MARKET: GREENWOOD					MARKET: MYRTLE BEACH					MARKET: DRANGEBURG				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED	416	457	535	612 659	DETACHED	375	439	520	556 608	DETACHED	422	487	567	650 699	DETACHED	354	416	479	537 580
SEMI-DETACHED/ROW	396	437	515	592 648	SEMI-DETACHED/ROW	356	420	501	537 590	SEMI-DETACHED/ROW	401	467	545	629 678	SEMI-DETACHED/ROW	337	399	462	521 564
WALKUP	386	427	494	576 623	WALKUP	347	410	482	524 567	WALKUP	391	454	524	608 651	WALKUP	329	391	450	509 548
ELEVATOR 2-4 STY	441	506	594		ELEVATOR 2-4 STY	431	488	581		ELEVATOR 2-4 STY	454	519	624		ELEVATOR 2-4 STY	418	470	542	
ELEVATOR 5+ STY	465	530	607		ELEVATOR 5+ STY	454	512	592		ELEVATOR 5+ STY	477	542	647		ELEVATOR 5+ STY	433	478	552	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: ROCKHILL					MARKET: COLUMBIA					MARKET: AIKEN					MARKET: ANDERSON				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED	424	470	530	597 653	DETACHED	405	475	547	612 669	DETACHED	386	453	506	551 602	DETACHED	369	432	482	545 597
SEMI-DETACHED/ROW	403	449	512	577 632	SEMI-DETACHED/ROW	385	455	530	592 648	SEMI-DETACHED/ROW	367	434	488	532 585	SEMI-DETACHED/ROW	351	413	465	528 578
WALKUP	392	433	495	562 612	WALKUP	375	445	506	576 628	WALKUP	358	425	475	519 566	WALKUP	341	404	453	515 557
ELEVATOR 2-4 STY	431	488	589		ELEVATOR 2-4 STY	441	506	594		ELEVATOR 2-4 STY	431	488	585		ELEVATOR 2-4 STY	440	502	556	
ELEVATOR 5+ STY	454	512	612		ELEVATOR 5+ STY	465	530	618		ELEVATOR 5+ STY	454	512	606		ELEVATOR 5+ STY	463	512	565	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: BEAUFORT					MARKET: CHARLESTON					MARKET: FLORENCE					MARKET: SPARTANBURG				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED	457	491	567	650 699	DETACHED	391	481	567	644 694	DETACHED	366	430	490	542 586	DETACHED	370	432	493	540 591
SEMI-DETACHED/ROW	436	470	545	629 678	SEMI-DETACHED/ROW	371	461	545	624 674	SEMI-DETACHED/ROW	348	412	473	526 570	SEMI-DETACHED/ROW	351	413	475	523 573
WALKUP	420	454	524	608 651	WALKUP	361	451	524	608 651	WALKUP	335	403	460	514 553	WALKUP	341	404	462	509 552
ELEVATOR 2-4 STY	454	519	624		ELEVATOR 2-4 STY	454	519	624		ELEVATOR 2-4 STY	431	488	566		ELEVATOR 2-4 STY	440	506	571	
ELEVATOR 5+ STY	477	542	647		ELEVATOR 5+ STY	477	542	647		ELEVATOR 5+ STY	454	512	587		ELEVATOR 5+ STY	463	522	581	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: NORTH AUGUSTA				
NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED	386	453	506	551 602
SEMI-DETACHED/ROW	367	434	488	532 585
WALKUP	358	425	475	519 566
ELEVATOR 2-4 STY	431	488	485	
ELEVATOR 5+ STY	454	512	606	
MANUFACTURED HOME				
EFFECTIVE DATE	100184			
TRENDING DATE	100186			



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 4

## GREENSBORO, NORTH CAROLINA AREA OFFICE

MARKET: GREENSBORO NUMBER OF BEDROOMS						MARKET: ASHEVILLE NUMBER OF BEDROOMS						MARKET: CHARLOTTE NUMBER OF BEDROOMS						MARKET: DURHAM NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			459	524	621	DETACHED			438	534	619	DETACHED			499	579	649	DETACHED			490	563	661
SEMI-DETACHED/ROW		370	443	493	592	SEMI-DETACHED/ROW		354	407	513	587	SEMI-DETACHED/ROW		392	465	538	622	SEMI-DETACHED/ROW		368	455	552	631
WALKUP	318	370	443	488	588	WALKUP	301	354	407	508	587	WALKUP	335	392	465	538	622	WALKUP	346	368	455	546	626
ELEVATOR 2-4 STY	338	403	468			ELEVATOR 2-4 STY	335	387	440			ELEVATOR 2-4 STY	359	419	498			ELEVATOR 2-4 STY	378	401	486		
ELEVATOR 5+ STY	482	518	627			ELEVATOR 5+ STY	438	493	582			ELEVATOR 5+ STY	484	519	622			ELEVATOR 5+ STY	481	523	636		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: GREENVILLE NUMBER OF BEDROOMS						MARKET: RALEIGH NUMBER OF BEDROOMS						MARKET: WINSTON-SALEM NUMBER OF BEDROOMS						MARKET: FAYETTEVILLE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			426	490	582	DETACHED			494	588	687	DETACHED			447	532	633	DETACHED			425	497	569
SEMI-DETACHED/ROW		342	412	464	536	SEMI-DETACHED/ROW		416	485	539	620	SEMI-DETACHED/ROW		361	417	494	571	SEMI-DETACHED/ROW		325	394	458	527
WALKUP	276	338	406	464	536	WALKUP	346	410	479	534	614	WALKUP	294	359	417	489	566	WALKUP	293	324	394	458	527
ELEVATOR 2-4 STY	306	359	427			ELEVATOR 2-4 STY	373	431	500			ELEVATOR 2-4 STY	321	380	445			ELEVATOR 2-4 STY	322	366	427		
ELEVATOR 5+ STY	413	479	574			ELEVATOR 5+ STY	524	589	699			ELEVATOR 5+ STY	461	493	591			ELEVATOR 5+ STY	404	454	539		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: WILMINGTON NUMBER OF BEDROOMS						MARKET: ELIZABETH CITY NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			439	519	590	DETACHED			455	539	648
SEMI-DETACHED/ROW		346	417	474	543	SEMI-DETACHED/ROW		319	403	491	594
WALKUP	298	346	417	474	543	WALKUP	269	314	398	486	589
ELEVATOR 2-4 STY	328	366	437			ELEVATOR 2-4 STY	294	359	459		
ELEVATOR 5+ STY	430	477	573			ELEVATOR 5+ STY	450	525	669		
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186				

## JACKSON, MISSISSIPPI AREA OFFICE

MARKET: JACKSON NUMBER OF BEDROOMS						MARKET: CORINTH NUMBER OF BEDROOMS						MARKET: GREENVILLE NUMBER OF BEDROOMS						MARKET: GREENWOOD NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			483	582	660	DETACHED			395	500	577	DETACHED			478	506	581	DETACHED			444	481	566
SEMI-DETACHED/ROW	353	383	477	564	635	SEMI-DETACHED/ROW	276	323	384	483	559	SEMI-DETACHED/ROW	362	391	453	491	571	SEMI-DETACHED/ROW	330	373	430	460	540
WALKUP	335	383	433	512	572	WALKUP	262	313	379	476	540	WALKUP	326	370	432	457	526	WALKUP	294	346	407	427	490
ELEVATOR 2-4 STY	472	535	622			ELEVATOR 2-4 STY	402	474	576			ELEVATOR 2-4 STY	423	516	620			ELEVATOR 2-4 STY	422	480	539		
ELEVATOR 5+ STY	486	552	642			ELEVATOR 5+ STY	416	491	598			ELEVATOR 5+ STY	435	531	640			ELEVATOR 5+ STY	436	496	553		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: GULFPORT NUMBER OF BEDROOMS						MARKET: HATTIESBURG NUMBER OF BEDROOMS						MARKET: SOUTHAVEN NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			449	526	602	DETACHED			433	517	598	DETACHED			471	545	621
SEMI-DETACHED/ROW	370	385	443	519	551	SEMI-DETACHED/ROW	302	354	419	501	572	SEMI-DETACHED/ROW	319	394	449	532	611
WALKUP	306	355	403	493	551	WALKUP	266	331	405	460	518	WALKUP	306	389	449	520	598
ELEVATOR 2-4 STY	455	535	631			ELEVATOR 2-4 STY	400	464	586			ELEVATOR 2-4 STY	440	518	622		
ELEVATOR 5+ STY	469	556	654			ELEVATOR 5+ STY	414	480	606			ELEVATOR 5+ STY	460	533	642		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

## JACKSONVILLE, FLORIDA AREA OFFICE

MARKET: JACKSONVILLE NUMBER OF BEDROOMS						MARKET: PENSACOLA NUMBER OF BEDROOMS						MARKET: KEY WEST NUMBER OF BEDROOMS						MARKET: MIAMI NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			607	684	762	DETACHED			566	639	708	DETACHED			687	759	835	DETACHED			687	759	835
SEMI-DETACHED/ROW	389	447	539	607	671	SEMI-DETACHED/ROW	401	457	537	607	680	SEMI-DETACHED/ROW	544	596	673	748	822	SEMI-DETACHED/ROW	544	596	673	748	822
WALKUP	349	395	491	573	645	WALKUP	313	365	438	505	573	WALKUP	410	468	583	689	760	WALKUP	410	468	583	689	760
ELEVATOR 2-4 STY	412	461	573			ELEVATOR 2-4 STY	360	420	499			ELEVATOR 2-4 STY	476	526	670			ELEVATOR 2-4 STY	476	526	670		
ELEVATOR 5+ STY	471	523	651			ELEVATOR 5+ STY	406	472	556			ELEVATOR 5+ STY	540	601	751			ELEVATOR 5+ STY	540	601	751		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: TAMPA NUMBER OF BEDROOMS						MARKET: ORLANDO NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			575	655	748	DETACHED			636	746	822
SEMI-DETACHED/ROW	397	454	545	616	689	SEMI-DETACHED/ROW	385	441	543	606	676
WALKUP	363	419	504	573	638	WALKUP	360	417	493	559	629
ELEVATOR 2-4 STY	444	503	610			ELEVATOR 2-4 STY	441	502	612		
ELEVATOR 5+ STY	524	584	693			ELEVATOR 5+ STY	512	571	676		
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186				



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 4

## LOUISVILLE, KENTUCKY AREA OFFICE

MARKET: LOUISVILLE						MARKET: COVINGTON						MARKET: OWENSBORO						MARKET: PADUCAH					
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			531	602	675	DETACHED			505	604	695	DETACHED			520	597	665	DETACHED			519	598	668
SEMI-DETACHED/ROW		443	508	571	638	SEMI-DETACHED/ROW		416	479	553	636	SEMI-DETACHED/ROW		398	481	571	638	SEMI-DETACHED/ROW		397	480	572	640
WALKUP	366	399	468	543	592	WALKUP	352	392	453	528	591	WALKUP	319	362	435	525	582	WALKUP	319	362	435	525	581
ELEVATOR 2-4 STY	398	431	499			ELEVATOR 2-4 STY	404	437	498			ELEVATOR 2-4 STY	398	418	499			ELEVATOR 2-4 STY	398	431	499		
ELEVATOR 5+ STY	477	523	624			ELEVATOR 5+ STY	490	530	636			ELEVATOR 5+ STY	452	507	620			ELEVATOR 5+ STY	451	509	608		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TREND DATE	100186					TREND DATE	100186					TREND DATE	100186					TREND DATE	100186				

MARKET: PIKEVILLE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			555	633	694
SEMI-DETACHED/ROW		435	519	587	645
WALKUP	370	412	474	543	593
ELEVATOR 2-4 STY	415	444	533		
ELEVATOR 5+ STY	478	524	636		
MANUFACTURED HOME					
EFFECTIVE DATE	100184				
TREND DATE	100186				

## KNOXVILLE, TENNESSEE AREA OFFICE

MARKET: KNOXVILLE						MARKET: CHATTANOOGA						MARKET: JOHNSON CITY						MARKET: KINGSFORD					
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			455	530	565	DETACHED			448	530	566	DETACHED			448	520	556	DETACHED			448	520	556
SEMI-DETACHED/ROW		381	439	510	555	SEMI-DETACHED/ROW		401	437	515	551	SEMI-DETACHED/ROW		366	437	509	545	SEMI-DETACHED/ROW		366	437	509	545
WALKUP	345	370	429	499	545	WALKUP	365	391	422	504	540	WALKUP	331	348	422	494	525	WALKUP	331	348	422	494	530
ELEVATOR 2-4 STY	370	396	455			ELEVATOR 2-4 STY	391	412	448			ELEVATOR 2-4 STY	361	379	453			ELEVATOR 2-4 STY	361	375	453		
ELEVATOR 5+ STY	396	417	482			ELEVATOR 5+ STY	412	437	473			ELEVATOR 5+ STY	384	407	478			ELEVATOR 5+ STY	381	407	478		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TREND DATE	100186					TREND DATE	100186					TREND DATE	100186					TREND DATE	100186				

MARKET: OAKRIDGE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			455	530	565
SEMI-DETACHED/ROW		381	439	510	555
WALKUP	345	370	429	499	545
ELEVATOR 2-4 STY	370	396	455		
ELEVATOR 5+ STY	396	417	482		
MANUFACTURED HOME					
EFFECTIVE DATE	100184				
TREND DATE	100186				

## NASHVILLE, TENNESSEE SERVICE OFFICE

MARKET: NASHVILLE						MARKET: CLARKSVILLE						MARKET: COLUMBIA						MARKET: MEMPHIS					
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			465	542	582	DETACHED			427	501	542	DETACHED			395	487	533	DETACHED			418	469	549
SEMI-DETACHED/ROW	356	395	449	530	571	SEMI-DETACHED/ROW	307	339	407	488	530	SEMI-DETACHED/ROW	308	314	371	479	512	SEMI-DETACHED/ROW	301	343	399	446	509
WALKUP	325	376	441	524	566	WALKUP	279	319	402	472	524	WALKUP	261	307	361	465	506	WALKUP	269	301	352	424	456
ELEVATOR 2-4 STY	335	395	449			ELEVATOR 2-4 STY	301	345	407			ELEVATOR 2-4 STY	267	325	368			ELEVATOR 2-4 STY	314	376	443		
ELEVATOR 5+ STY	342	409	465			ELEVATOR 5+ STY	307	366	426			ELEVATOR 5+ STY	278	348	402			ELEVATOR 5+ STY	353	417	484		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TREND DATE	100186					TREND DATE	100186					TREND DATE	100186					TREND DATE	100186				

MARKET: JACKSON						MARKET: UNION CITY					
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			399	465	548	DETACHED			381	443	523
SEMI-DETACHED/ROW	279	319	374	432	502	SEMI-DETACHED/ROW	303	303	358	412	478
WALKUP	262	301	364	421	479	WALKUP	251	288	347	402	457
ELEVATOR 2-4 STY	321	345	433			ELEVATOR 2-4 STY	305	364	462		
ELEVATOR 5+ STY	334	382	471			ELEVATOR 5+ STY	334	404	471		
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TREND DATE	100186					TREND DATE	100186				



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 5

## CHICAGO, ILLINOIS AREA OFFICE

MARKET: CHICAGO NUMBER OF BEDROOMS						MARKET: BELLEVILLE NUMBER OF BEDROOMS						MARKET: MOLINE NUMBER OF BEDROOMS						MARKET: SPRINGFIELD NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED						DETACHED						DETACHED					
SEMI-DETACHED/ROW	535	601	679	798	884	SEMI-DETACHED/ROW	394	444	532	818	721	SEMI-DETACHED/ROW	430	463	570	696	785	SEMI-DETACHED/ROW	371	423	507	593	689
WALKUP	454	524	626	750	787	WALKUP	380	431	504	569	629	WALKUP	380	442	531	656	694	WALKUP	336	396	470	559	638
ELEVATOR 2-4 STY	485	570	672	799	800	ELEVATOR 2-4 STY	392	463	539			ELEVATOR 2-4 STY	453	469	564			ELEVATOR 2-4 STY	405	468	542		
ELEVATOR 5+ STY	525	657	781	810	857	ELEVATOR 5+ STY	462	507	589			ELEVATOR 5+ STY	466	530	636			ELEVATOR 5+ STY	453	508	595		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

MARKET: EAST ST. LOUIS NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED					
SEMI-DETACHED/ROW	380	429	493	566	652
WALKUP	339	392	466	530	589
ELEVATOR 2-4 STY	361	418	504		
ELEVATOR 5+ STY	436	495	596		
MANUFACTURED HOME					
EFFECTIVE DATE	100184				
TRENDED DATE	100186				

## CINCINNATI, OHIO SERVICE OFFICE

MARKET: CINCINNATI NUMBER OF BEDROOMS						MARKET: DAYTON NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED					
SEMI-DETACHED/ROW		468	533	639	703	SEMI-DETACHED/ROW		403	468	561	632
WALKUP	328	386	466	553	638	WALKUP	315	393	460	526	588
ELEVATOR 2-4 STY	361	482	574			ELEVATOR 2-4 STY	367	487	582		
ELEVATOR 5+ STY	502	591	672			ELEVATOR 5+ STY	508	597	645		
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186				

## CLEVELAND, OHIO SERVICE OFFICE

MARKET: CLEVELAND NUMBER OF BEDROOMS						MARKET: AKRON NUMBER OF BEDROOMS						MARKET: FINDLAY NUMBER OF BEDROOMS						MARKET: LORAIN NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED						DETACHED						DETACHED					
SEMI-DETACHED/ROW		495	566	639	687	SEMI-DETACHED/ROW		478	546	625	666	SEMI-DETACHED/ROW		405	451	547	586	SEMI-DETACHED/ROW		369	437	511	550
WALKUP	355	415	495	575	624	WALKUP	350	399	468	559	595	WALKUP	312	337	396	482	524	WALKUP	267	294	361	453	491
ELEVATOR 2-4 STY	364	432	542			ELEVATOR 2-4 STY	347	389	438			ELEVATOR 2-4 STY	312	337	440			ELEVATOR 2-4 STY	337	355	422		
ELEVATOR 5+ STY	427	440	552			ELEVATOR 5+ STY	355	416	471			ELEVATOR 5+ STY	357	409	503			ELEVATOR 5+ STY	355	360	439		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

MARKET: MANSFIELD NUMBER OF BEDROOMS						MARKET: TOLEDO NUMBER OF BEDROOMS						MARKET: YOUNGSTOWN NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED						DETACHED					
SEMI-DETACHED/ROW		428	472	543	604	SEMI-DETACHED/ROW		446	510	585	624	SEMI-DETACHED/ROW		390	451	526	541
WALKUP	313	336	382	474	510	WALKUP	331	367	434	530	563	WALKUP	280	316	375	470	513
ELEVATOR 2-4 STY	345	379	453			ELEVATOR 2-4 STY	352	382	467			ELEVATOR 2-4 STY	314	331	412		
ELEVATOR 5+ STY	351	403	463			ELEVATOR 5+ STY	386	391	476			ELEVATOR 5+ STY	321	338	420		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

## DETROIT, MICHIGAN AREA OFFICE

MARKET: DETROIT NUMBER OF BEDROOMS						MARKET: FLINT NUMBER OF BEDROOMS						MARKET: SAGINAW NUMBER OF BEDROOMS						MARKET: ANN ARBOR NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED						DETACHED						DETACHED					
SEMI-DETACHED/ROW		379	496	595	655	SEMI-DETACHED/ROW		336	454	512	570	SEMI-DETACHED/ROW		336	454	512	570	SEMI-DETACHED/ROW		379	496	595	655
WALKUP	309	379	466	510	570	WALKUP	284	327	393	512	570	WALKUP	284	327	393	512	570	WALKUP	309	379	466	510	570
ELEVATOR 2-4 STY	347	408	484			ELEVATOR 2-4 STY	293	359	399			ELEVATOR 2-4 STY	293	359	399			ELEVATOR 2-4 STY	347	408	484		
ELEVATOR 5+ STY	346	444	504			ELEVATOR 5+ STY	296	371	436			ELEVATOR 5+ STY	296	371	436			ELEVATOR 5+ STY	346	444	504		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

MARKET: YPSILANTI NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED					
SEMI-DETACHED/ROW		379	496	595	655
WALKUP	309	379	466	510	570
ELEVATOR 2-4 STY	347	408	484		
ELEVATOR 5+ STY	346	444	504		
MANUFACTURED HOME					
EFFECTIVE DATE	100184				
TRENDED DATE	100186				



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 5

## GRAND RAPIDS, MICHIGAN SERVICE OFFICE

MARKET: MT PLEASANT NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			558	661	704
SEMI-DETACHED/ROW			412	474	587
WALKUP	251	335	374	465	500
ELEVATOR 2-4 STY	259	351	391		
ELEVATOR 5+ STY	421	479	555		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: GRAND RAPIDS NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			554	655	687
SEMI-DETACHED/ROW			387	477	585
WALKUP	281	350	444	487	521
ELEVATOR 2-4 STY	298	368	460		
ELEVATOR 5+ STY	405	472	524		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: BENTON HARBOR NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			532	632	665
SEMI-DETACHED/ROW			390	486	584
WALKUP	272	316	390	477	507
ELEVATOR 2-4 STY	289	332	406		
ELEVATOR 5+ STY	393	451	516		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: BATTLE CREEK NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED				579	662
SEMI-DETACHED/ROW			425	525	615
WALKUP	271	352	428	523	552
ELEVATOR 2-4 STY	289	369	445		
ELEVATOR 5+ STY	416	482	540		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: LANSING NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			556	683	723
SEMI-DETACHED/ROW			389	465	574
WALKUP	299	351	425	512	543
ELEVATOR 2-4 STY	316	368	441		
ELEVATOR 5+ STY	376	425	499		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: MUSKEGON NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			562	663	696
SEMI-DETACHED/ROW			437	519	609
WALKUP	286	361	427	506	517
ELEVATOR 2-4 STY	303	380	444		
ELEVATOR 5+ STY	413	482	535		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: TRAVERSE CITY NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			601	703	736
SEMI-DETACHED/ROW			451	528	648
WALKUP	289	374	423	519	557
ELEVATOR 2-4 STY	304	390	439		
ELEVATOR 5+ STY	456	527	584		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: MARQUETTE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED				522	625
SEMI-DETACHED/ROW			380	476	573
WALKUP	215	300	387	481	517
ELEVATOR 2-4 STY	231	316	403		
ELEVATOR 5+ STY	420	491	505		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: JACKSON NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			544	663	713
SEMI-DETACHED/ROW			376	455	562
WALKUP	292	362	414	508	535
ELEVATOR 2-4 STY	298	379	431		
ELEVATOR 5+ STY	432	493	558		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

## INDIANAPOLIS, INDIANA AREA OFFICE

MARKET: INDIANAPOLIS NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			571	636	707
SEMI-DETACHED/ROW			406	485	552
WALKUP	333	374	447	510	530
ELEVATOR 2-4 STY	368	397	474		
ELEVATOR 5+ STY	453	501	588		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: BLOOMINGTON NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			542	607	677
SEMI-DETACHED/ROW			385	459	521
WALKUP	315	357	425	482	534
ELEVATOR 2-4 STY	349	374	453		
ELEVATOR 5+ STY	434	482	570		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: EVANSVILLE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			528	593	660
SEMI-DETACHED/ROW			390	466	534
WALKUP	311	353	425	482	532
ELEVATOR 2-4 STY	347	376	453		
ELEVATOR 5+ STY	420	470	554		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: FORT WAYNE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED				535	597
SEMI-DETACHED/ROW			384	459	509
WALKUP	312	352	418	468	515
ELEVATOR 2-4 STY	345	374	445		
ELEVATOR 5+ STY	432	478	559		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: HAMMOND NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			584	653	711
SEMI-DETACHED/ROW			444	520	583
WALKUP	354	413	481	548	584
ELEVATOR 2-4 STY	405	435	506		
ELEVATOR 5+ STY	474	532	613		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: LAFAYETTE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			584	632	677
SEMI-DETACHED/ROW			401	469	536
WALKUP	326	367	434	490	540
ELEVATOR 2-4 STY	359	389	462		
ELEVATOR 5+ STY	449	498	582		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: SOUTH BEND NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			558	627	701
SEMI-DETACHED/ROW			415	482	550
WALKUP	324	368	432	488	538
ELEVATOR 2-4 STY	362	392	461		
ELEVATOR 5+ STY	443	501	580		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: TERRE HAUTE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED				558	627
SEMI-DETACHED/ROW			399	478	541
WALKUP	322	366	440	503	557
ELEVATOR 2-4 STY	357	388	468		
ELEVATOR 5+ STY	436	487	575		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: GARY NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			584	643	709
SEMI-DETACHED/ROW			444	512	583
WALKUP	364	413	481	548	584
ELEVATOR 2-4 STY	405	435	506		
ELEVATOR 5+ STY	461	511	582		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 5

## MILWAUKEE, WISCONSIN AREA OFFICE

MARKET: MADISON NUMBER OF BEDROOMS						MARKET: REEDSVILLE NUMBER OF BEDROOMS						MARKET: SUPERIOR NUMBER OF BEDROOMS						MARKET: MILWAUKEE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			632	718	758				600	680	724				614	708	759				683	748	828
SEMI-DETACHED/ROW		461	541	655	697		439	507	623	670			454	514	624	678			536	587	716	754	
WALKUP	350	400	483	591		326	379	452	563			338	392	454	577			389	443	520	642		
ELEVATOR 2-4 STY	366	418	503			343	396	469				355	409	471				406	460	537			
ELEVATOR 5+ STY	502	546	658			476	529	623				480	549	646				538	604	717			
MANUFACTURED HOME																							
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: EAU CLAIRE NUMBER OF BEDROOMS						MARKET: GREEN BAY NUMBER OF BEDROOMS						MARKET: WAUSAU NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			552	639	685				569	664	706				543	661	691
SEMI-DETACHED/ROW		422	481	591	636		417	490	602	647			422	485	599	644	
WALKUP	320	367	430	539		309	358	433	539			312	362	429	534		
ELEVATOR 2-4 STY	339	387	450			328	375	451				329	379	447			
ELEVATOR 5+ STY	464	509	604			455	496	610				457	512	608			
MANUFACTURED HOME																	
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

## MINNEAPOLIS-ST. PAUL, MINNESOTA AREA OFFICE

MARKET: MINNEAPOLIS NUMBER OF BEDROOMS						MARKET: DULUTH NUMBER OF BEDROOMS						MARKET: MANKATO NUMBER OF BEDROOMS						MARKET: ROCHESTER NUMBER OF BEDROOMS						
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	
DETACHED																								
SEMI-DETACHED/ROW			404	541	622	695			403	524	595	667			412	518	589	659			432	522	605	676
WALKUP	330	379	452	577	598		334	374	453	536	571		324	362	451	520	550		331	369	455	524	555	
ELEVATOR 2-4 STY	366	434	544				364	419	532				358	397	465				361	400	472			
ELEVATOR 5+ STY	373	493	622				364	454	567				371	509	603				390	529	599			
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					
NO MARKET CODE MATCH IN PRT 54613																								
MARKET: ST. CLOUD NUMBER OF BEDROOMS						MARKET: WORTHINGTON NUMBER OF BEDROOMS																		
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+													
DETACHED																								
SEMI-DETACHED/ROW			353	471	535	598			314	435	495	553												
WALKUP	293	328	407	490	520		268	295	380	458	486													
ELEVATOR 2-4 STY	318	393	451				285	349	416															
ELEVATOR 5+ STY	318	453	534				290	404	493															
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184																	
TRENDED DATE	100186					TRENDED DATE	100186																	



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 6

## DALLAS, TEXAS AREA OFFICE

MARKET: DALLAS					MARKET: SHERMAN					MARKET: TYLER					MARKET: WACO				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
STRUCTURE TYPE																			
DETACHED		567	662	786			437	525	595			585	588	655			455	538	694
SEMI-DETACHED/ROW	413	522	615	668		306	399	478	548			373	472	551	618		328	414	488
WALKUP	322	397	496	572	650	249	295	379	437	589	283	335	443	517	578	258	315	393	453
ELEVATOR 2-4 STY	339	427	538			268	326	418			304	385	486			268	337	427	528
ELEVATOR 5+ STY	476	548	695			364	435	569			438	494	659			378	453	592	
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: WICHITA FALLS					MARKET: SAN ANGELO					MARKET: ABILENE					MARKET: LUBBOCK				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
STRUCTURE TYPE																			
DETACHED		468	553	623			497	618	697			539	657	727			485	568	637
SEMI-DETACHED/ROW		417	511	573			442	534	623			378	469	553	644		351	442	522
WALKUP	278	312	388	492	566	276	328	413	497	578	292	347	449	515	598	278	313	428	485
ELEVATOR 2-4 STY	285	366	434			291	378	459			384	383	482			285	362	456	564
ELEVATOR 5+ STY	418	471	638			414	479	656			428	515	688			484	472	683	
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: AMARILLO					MARKET: EL PASO					MARKET: MIDLAND					MARKET: ODESSA				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
STRUCTURE TYPE																			
DETACHED		478	555	624			471	545	611			463	789	774			463	789	774
SEMI-DETACHED/ROW	345	435	512	592		339	429	505	571			358	488	592	692		358	488	592
WALKUP	268	318	413	476	556	266	318	486	469	547	267	389	379	558	641	267	389	379	558
ELEVATOR 2-4 STY	283	356	448			278	358	441			282	363	425			282	363	425	
ELEVATOR 5+ STY	397	469	595			391	469	595			416	468	622			419	468	622	
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: ALBUQUERQUE NM					MARKET: SANTA FE NM					MARKET: SILVER CITY NM					MARKET: TAOS NM				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
STRUCTURE TYPE																			
DETACHED		493	575	642			545	788	778			478	558	623			582	586	654
SEMI-DETACHED/ROW	352	447	525	608	342	377	475	568	653			358	456	532	598		347	437	518
WALKUP	277	324	421	488	569	296	358	451	521	687	292	348	439	588	553	271	325	416	481
ELEVATOR 2-4 STY	291	364	457			389	388	489			389	374	473			285	358	451	
ELEVATOR 5+ STY	487	475	638			434	521	693			487	461	611			481	481	648	
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: CLOVIS NM					MARKET: BEAUMONT					MARKET: BRYAN					MARKET: LUFKIN				
NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS					NUMBER OF BEDROOMS				
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
STRUCTURE TYPE																			
DETACHED		531	721	789			572	672	801			531	702	814			506	594	688
SEMI-DETACHED/ROW	353	396	498	616	671	344	406	481	589			339	410	506	638		310	364	473
WALKUP	387	378	465	598	627	324	374	461	571			320	380	489	580		293	347	436
ELEVATOR 2-4 STY	319	486	583			381	450	553			373	451	562			337	399	524	
ELEVATOR 5+ STY	424	499	638			512	544	661			494	593	741			473	515	632	
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 6

## LITTLE ROCK, ARKANSAS AREA OFFICE

MARKET: FAYETTEVILLE NUMBER OF BEDROOMS						MARKET: LITTLE ROCK NUMBER OF BEDROOMS						MARKET: TEXARKANA NUMBER OF BEDROOMS						MARKET: FORT SMITH NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			487	575	638	DETACHED			508	588	667	DETACHED			468	584	661	DETACHED			451	545	622
SEMI-DETACHED/ROW	326	396	464	548	610	SEMI-DETACHED/ROW	340	406	483	558	629	SEMI-DETACHED/ROW	317	364	451	546	608	SEMI-DETACHED/ROW	302	341	433	500	560
WALKUP	311	369	442	522	578	WALKUP	315	396	447	549	612	WALKUP	307	354	436	537	588	WALKUP	284	330	399	473	534
ELEVATOR 2-4 STY	338	396	475			ELEVATOR 2-4 STY	344	426	483			ELEVATOR 2-4 STY	335	382	471			ELEVATOR 2-4 STY	312	359	439		
ELEVATOR 5+ STY	406	474	545			ELEVATOR 5+ STY	409	477	556			ELEVATOR 5+ STY	406	474	546			ELEVATOR 5+ STY	413	476	560		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: JONESBORO NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			455	555	630
SEMI-DETACHED/ROW	311	361	442	541	591
WALKUP	293	347	418	510	557
ELEVATOR 2-4 STY	324	376	464		
ELEVATOR 5+ STY	400	468	544		
MANUFACTURED HOME					
EFFECTIVE DATE	100184				
TRENDING DATE	100186				

## NEW ORLEANS, LOUISIANA AREA OFFICE

MARKET: NEW ORLEANS NUMBER OF BEDROOMS						MARKET: LAKE CHARLES NUMBER OF BEDROOMS						MARKET: LAFAYETTE NUMBER OF BEDROOMS						MARKET: BATON ROUGE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			505	600	686				445	551	640				454	551	637				436	556	646
SEMI-DETACHED/ROW		410	500	595	674		369		442	545	628		369		451	545	625		365		431	550	634
WALKUP	312	389	471	579	648	291	345	416	515	582		301	358	439	533	601		279	328	390	502	565	
ELEVATOR 2-4 STY	324	407	503			315	369	440				321	382	463				303	352	414			
ELEVATOR 5+ STY	481	570	662			454	514	627				472	527	654				447	506	611			
MANUFACTURED HOME																							
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

MARKET: HOUMA NUMBER OF BEDROOMS						MARKET: SHREVEPORT NUMBER OF BEDROOMS						MARKET: ALEXANDRIA NUMBER OF BEDROOMS						MARKET: MONROE NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			398	491	577				469	558	648				416	489	568				428	538	615
SEMI-DETACHED/ROW		334	395	485	570	335	347	447	535	620		299	331	389	460	546		298	330	399	509	597	
WALKUP	264	320	381	470	542	270	318	415	497	562		268	314	374	441	514		271	318	392	508	574	
ELEVATOR 2-4 STY	288	344	405			323	382	434				289	342	394				296	365	410			
ELEVATOR 5+ STY	429	492	598			410	468	599				404	458	574				409	463	575			
MANUFACTURED HOME																							
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186				

NO MARKET CODE MATCH IN PRT		65600
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NO MARKET CODE MATCH IN PRT 65600



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 6

## OKLAHOMA CITY, OKLAHOMA AREA OFFICE

MARKET: OKLAHOMA CITY					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			564	641	745
SEMI-DETACHED/ROW		416	465	564	623
WALKUP	333	367	455	525	609
ELEVATOR 2-4 STY	351	392	492		
ELEVATOR 5+ STY	420	461	564		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: ADA					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			499	589	642
SEMI-DETACHED/ROW		381	485	574	628
WALKUP	298	323	418	481	532
ELEVATOR 2-4 STY	320	346	448		
ELEVATOR 5+ STY	345	381	492		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: ARDMORE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			497	586	639
SEMI-DETACHED/ROW		374	482	571	625
WALKUP	290	320	418	481	529
ELEVATOR 2-4 STY	316	346	443		
ELEVATOR 5+ STY	345	381	492		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: ENID					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			496	576	642
SEMI-DETACHED/ROW		407	475	563	628
WALKUP	260	324	383	465	513
ELEVATOR 2-4 STY	292	348	417		
ELEVATOR 5+ STY	316	410	485		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: GUYMON					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			455	543	610
SEMI-DETACHED/ROW		360	440	527	593
WALKUP	270	300	374	452	499
ELEVATOR 2-4 STY	283	318	414		
ELEVATOR 5+ STY	327	362	447		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: LAWTON					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			507	573	657
SEMI-DETACHED/ROW		394	486	561	643
WALKUP	276	318	404	486	551
ELEVATOR 2-4 STY	293	341	439		
ELEVATOR 5+ STY	359	408	509		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: SHAWNEE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			437	481	530
SEMI-DETACHED/ROW		357	426	468	515
WALKUP	267	297	360	392	429
ELEVATOR 2-4 STY	278	314	398		
ELEVATOR 5+ STY	323	359	431		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: STILLWATER					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			452	521	587
SEMI-DETACHED/ROW		373	438	507	568
WALKUP	265	315	373	434	479
ELEVATOR 2-4 STY	287	334	409		
ELEVATOR 5+ STY	322	379	445		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: WOODWARD					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			484	578	634
SEMI-DETACHED/ROW		375	472	558	621
WALKUP	279	319	389	466	514
ELEVATOR 2-4 STY	296	336	424		
ELEVATOR 5+ STY	346	381	477		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: BARTLESVILLE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			439	517	573
SEMI-DETACHED/ROW		351	427	502	559
WALKUP	257	297	367	440	481
ELEVATOR 2-4 STY	274	320	376		
ELEVATOR 5+ STY	307	339	427		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: MC ALESTER					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			436	506	558
SEMI-DETACHED/ROW		319	424	493	544
WALKUP	224	253	351	410	454
ELEVATOR 2-4 STY	235	269	389		
ELEVATOR 5+ STY	280	314	417		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: MUSKOGEE					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			397	458	519
SEMI-DETACHED/ROW		352	383	445	504
WALKUP	249	287	319	395	428
ELEVATOR 2-4 STY	266	303	331		
ELEVATOR 5+ STY	314	347	379		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: TULSA					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			506	675	751
SEMI-DETACHED/ROW		345	419	565	615
WALKUP	278	315	407	565	615
ELEVATOR 2-4 STY	296	339	444		
ELEVATOR 5+ STY	364	408	517		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

## SAN ANTONIO, TEXAS AREA OFFICE

MARKET: SAN ANTONIO					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			615	729	831
SEMI-DETACHED/ROW	354	419	540	625	752
WALKUP	304	358	454	513	651
ELEVATOR 2-4 STY	372	437	573		
ELEVATOR 5+ STY	509	606	820		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: AUSTIN					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			644	772	859
SEMI-DETACHED/ROW	373	452	578	699	821
WALKUP	323	386	479	579	688
ELEVATOR 2-4 STY	396	470	606		
ELEVATOR 5+ STY	540	650	875		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: CORPUS CHRISTI					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			620	771	898
SEMI-DETACHED/ROW	376	458	584	693	816
WALKUP	326	393	482	578	684
ELEVATOR 2-4 STY	397	470	607		
ELEVATOR 5+ STY	537	646	872		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: EAGLE PASS					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			584	760	806
SEMI-DETACHED/ROW	351	430	539	678	774
WALKUP	299	357	429	534	638
ELEVATOR 2-4 STY	382	441	558		
ELEVATOR 5+ STY	527	629	826		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: HARLINGEN					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			594	730	857
SEMI-DETACHED/ROW	344	424	541	674	788
WALKUP	291	347	421	522	619
ELEVATOR 2-4 STY	359	422	551		
ELEVATOR 5+ STY	511	619	830		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: LAREDO					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			571	745	809
SEMI-DETACHED/ROW	342	420	526	663	774
WALKUP	291	347	416	519	619
ELEVATOR 2-4 STY	373	432	545		
ELEVATOR 5+ STY	519	620	828		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: VICTORIA					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			621	771	898
SEMI-DETACHED/ROW	399	486	593	693	816
WALKUP	349	421	517	630	732
ELEVATOR 2-4 STY	420	498	642		
ELEVATOR 5+ STY	560	674	897		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186

MARKET: DEL RIO					
NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			579	756	809
SEMI-DETACHED/ROW	348	427	535	674	774
WALKUP	296	354	425	530	628
ELEVATOR 2-4 STY	379	438	554		
ELEVATOR 5+ STY	524	626	834		
MANUFACTURED HOME					

EFFECTIVE DATE 100184  
TRENDED DATE 100186



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 7

## DES MOINES, IOWA SERVICE OFFICE

MARKET: DES MOINES NUMBER OF BEDROOMS						MARKET: BETTENDORF NUMBER OF BEDROOMS						MARKET: CEDAR RAPIDS NUMBER OF BEDROOMS						MARKET: COUNCIL BLUFF NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			584	674	772	DETACHED			593	683	787	DETACHED			593	683	783	DETACHED			533	618	714
SEMI-DETACHED/ROW		421	505	568	650	SEMI-DETACHED/ROW		437	515	577	661	SEMI-DETACHED/ROW		418	496	566	651	SEMI-DETACHED/ROW		402	481	541	615
WALKUP	323	370	431	485	537	WALKUP	330	359	439	496	551	WALKUP	323	348	427	493	559	WALKUP	301	347	408	456	505
ELEVATOR 2-4 STY	389	431	509			ELEVATOR 2-4 STY	396	439	518			ELEVATOR 2-4 STY	395	438	517			ELEVATOR 2-4 STY	382	433	498		
ELEVATOR 5+ STY	419	467	554			ELEVATOR 5+ STY	427	476	565			ELEVATOR 5+ STY	426	475	564			ELEVATOR 5+ STY	415	469	555		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: DUBUQUE NUMBER OF BEDROOMS						MARKET: MASON CITY NUMBER OF BEDROOMS						MARKET: SIOUX CITY NUMBER OF BEDROOMS						MARKET: DAVENPORT NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			593	683	783	DETACHED			570	651	740	DETACHED			577	658	751	DETACHED			593	683	787
SEMI-DETACHED/ROW		429	515	576	661	SEMI-DETACHED/ROW		429	515	577	661	SEMI-DETACHED/ROW		427	512	575	659	SEMI-DETACHED/ROW		437	515	577	661
WALKUP	325	325	411	505	561	WALKUP	296	340	412	474	541	WALKUP	305	341	414	475	552	WALKUP	330	359	439	496	551
ELEVATOR 2-4 STY	392	436	513			ELEVATOR 2-4 STY	389	433	510			ELEVATOR 2-4 STY	391	436	513			ELEVATOR 2-4 STY	396	439	518		
ELEVATOR 5+ STY	422	473	561			ELEVATOR 5+ STY	422	473	561			ELEVATOR 5+ STY	422	473	560			ELEVATOR 5+ STY	427	476	565		
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: WATERLOO NUMBER OF BEDROOMS						MARKET: KANSAS CITY NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED			594	683	783	DETACHED			394	435	521
SEMI-DETACHED/ROW		429	513	576	661	SEMI-DETACHED/ROW		321	378	460	567
WALKUP	325	325	413	505	561	WALKUP		353	395	520	
ELEVATOR 2-4 STY	392	436	513			ELEVATOR 2-4 STY		446	492	652	
ELEVATOR 5+ STY	422	473	561			ELEVATOR 5+ STY					
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186				

## KANSAS CITY, MISSOURI AREA OFFICE

MARKET: KANSAS CITY NUMBER OF BEDROOMS						MARKET: JOPLIN NUMBER OF BEDROOMS						MARKET: ST. JOSEPH NUMBER OF BEDROOMS						MARKET: SEDALIA NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED			294	333	432	DETACHED			305	346	435	DETACHED			291	335	417
SEMI-DETACHED/ROW		394	435	521	586	SEMI-DETACHED/ROW		245	292	374	482	SEMI-DETACHED/ROW		281	324	402	498	SEMI-DETACHED/ROW		274	318	400	466
WALKUP	321	378	460	567	605	WALKUP		309	355	442		WALKUP		318	365	456		WALKUP		323	370	463	
ELEVATOR 2-4 STY	353	395	520			ELEVATOR 2-4 STY		402	453	591		ELEVATOR 2-4 STY		414	468	609		ELEVATOR 2-4 STY		420	474	619	
ELEVATOR 5+ STY	446	492	652			ELEVATOR 5+ STY						ELEVATOR 5+ STY						ELEVATOR 5+ STY					
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: SPRINGFIELD NUMBER OF BEDROOMS						MARKET: TOPEKA NUMBER OF BEDROOMS						MARKET: GARDEN CITY NUMBER OF BEDROOMS						MARKET: PITTSBURG NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED			309	365	443	DETACHED			358	358	428	DETACHED			320	346	415
SEMI-DETACHED/ROW		276	299	401	485	SEMI-DETACHED/ROW		291	313	409	496	SEMI-DETACHED/ROW		287	336	428	486	SEMI-DETACHED/ROW		266	306	366	461
WALKUP	231	279	378	475	519	WALKUP		336	389	483		WALKUP		328	379	473		WALKUP		322	373	466	
ELEVATOR 2-4 STY	275	316	395			ELEVATOR 2-4 STY		402	453	592		ELEVATOR 2-4 STY		391	440	576		ELEVATOR 2-4 STY		384	433	567	
ELEVATOR 5+ STY	359	405	527			ELEVATOR 5+ STY						ELEVATOR 5+ STY						ELEVATOR 5+ STY					
MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186				

MARKET: SALINA NUMBER OF BEDROOMS						MARKET: WICHITA NUMBER OF BEDROOMS					
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+
DETACHED						DETACHED			337	403	472
SEMI-DETACHED/ROW		306	349	424	530	SEMI-DETACHED/ROW		265	302	408	500
WALKUP	263	304	390	467	530	WALKUP		334	386	483	
ELEVATOR 2-4 STY	328	383	473			ELEVATOR 2-4 STY		398	449	587	
ELEVATOR 5+ STY	391	440	576			ELEVATOR 5+ STY					
MANUFACTURED HOME						MANUFACTURED HOME					
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184				
TRENDING DATE	100186					TRENDING DATE	100186				



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 7

## OMAHA, NEBRASKA AREA OFFICE

STRUCTURE TYPE	MARKET: OMAHA NUMBER OF BEDROOMS					MARKET: GRAND ISLAND NUMBER OF BEDROOMS					MARKET: LINCOLN NUMBER OF BEDROOMS					MARKET: NORFOLK NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		363	463	527	580		359	454	521	574		355	449	515	567		359	454	521	574
WALKUP	281	339	418	517	546	281	338	418	517	563	280	339	418	510	562	281	338	418	517	563
ELEVATOR 2-4 STY	288	381	458			288	376	458			288	383	458			288	376	458		
ELEVATOR 5+ STY	316	394	474			319	394	474			328	394	474			319	394	474		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: NORTH PLATTE NUMBER OF BEDROOMS					MARKET: SCOTTS BLUFF NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED										
SEMI-DETACHED/ROW		331	419	481	530		353	447	512	564
WALKUP	263	328	386	479	521	280	344	418	510	561
ELEVATOR 2-4 STY	275	348	438			292	370	467		
ELEVATOR 5+ STY	295	372	458			314	397	487		
MANUFACTURED HOME										
EFFECTIVE DATE					100184					100184
TRENDING DATE					100186					100186

## ST. LOUIS, MISSOURI AREA OFFICE

STRUCTURE TYPE	MARKET: ST. LOUIS NUMBER OF BEDROOMS					MARKET: CAPE GIRARDEAU NUMBER OF BEDROOMS					MARKET: COLUMBIA NUMBER OF BEDROOMS					MARKET: KIRKSVILLE NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+
DETACHED																				
SEMI-DETACHED/ROW		474	561	664	731		326	405	489	535		333	409	505	551		337	417	526	574
WALKUP	349	441	526	596	657	244	307	364	432	449	258	327	397	480	529	253	320	403	488	538
ELEVATOR 2-4 STY	379	475	568			270	338	408			279	351	428			275	345	435		
ELEVATOR 5+ STY	422	548	740			298	367	543			311	415	572			306	408	582		
MANUFACTURED HOME																				
EFFECTIVE DATE					100184					100184					100184					100184
TRENDING DATE					100186					100186					100186					100186

STRUCTURE TYPE	MARKET: ROLLA NUMBER OF BEDROOMS				
	-0-	-1-	-2-	-3-	-4+
DETACHED					
SEMI-DETACHED/ROW		334	425	512	567
WALKUP	249	315	397	479	525
ELEVATOR 2-4 STY	270	339	428		
ELEVATOR 5+ STY	301	394	573		
MANUFACTURED HOME					
EFFECTIVE DATE					100184
TRENDING DATE					100186



**SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)**

## REGION 8

## DENVER, COLORADO REGIONAL AREA OFFICE

MARKET: DENVER, CO NUMBER OF BEDROOMS					MARKET: GRAND JUNCT, CO NUMBER OF BEDROOMS					MARKET: ASPEN/VAIL NUMBER OF BEDROOMS					MARKET: FARGO, ND NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			612	662 723	DETACHED			545	620 661	DETACHED			562	642 680	DETACHED			536	636 684
SEMI-DETACHED/ROW	400	454	540	619 653	SEMI-DETACHED/ROW	313	359	438	550 631	SEMI-DETACHED/ROW	346	398	482	590 634	SEMI-DETACHED/ROW	333	387	472	591 644
WALKUP	341	389	462	577 642	WALKUP	285	341	400	501 576	WALKUP	319	376	445	548 596	WALKUP	268	365	434	465 625
ELEVATOR 2-4 STY	341	395	472		ELEVATOR 2-4 STY	352	402	489		ELEVATOR 2-4 STY	369	434	483		ELEVATOR 2-4 STY	353	421	502	
ELEVATOR 5+ STY	352	429	542		ELEVATOR 5+ STY	376	427	503		ELEVATOR 5+ STY	381	444	492		ELEVATOR 5+ STY	364	429	527	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: BISMARCK, ND NUMBER OF BEDROOMS					MARKET: DICKENSON, ND NUMBER OF BEDROOMS					MARKET: HELENA, MT NUMBER OF BEDROOMS					MARKET: BILLINGS, MT NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			536	603 643	DETACHED			463	570 645	DETACHED			436	515 553	DETACHED			521	592 629
SEMI-DETACHED/ROW	324	392	466	546 593	SEMI-DETACHED/ROW	276	318	385	482 552	SEMI-DETACHED/ROW	279	332	411	505 543	SEMI-DETACHED/ROW	333	389	479	581 620
WALKUP	299	370	428	520 587	WALKUP	254	283	351	440 504	WALKUP	251	332	373	479 535	WALKUP	304	367	441	546 610
ELEVATOR 2-4 STY	361	401	505		ELEVATOR 2-4 STY	306	345	425		ELEVATOR 2-4 STY	309	373	438		ELEVATOR 2-4 STY	337	398	519	
ELEVATOR 5+ STY	386	435	521		ELEVATOR 5+ STY	314	360	435		ELEVATOR 5+ STY	322	389	451		ELEVATOR 5+ STY	350	412	528	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: GREAT FALLS, MT NUMBER OF BEDROOMS					MARKET: MISSOULA, MT NUMBER OF BEDROOMS					MARKET: SALT LAKE CITY NUMBER OF BEDROOMS					MARKET: CEDAR CITY, UT NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			462	532 571	DETACHED			448	527 568	DETACHED			517	649 713	DETACHED			460	504 548
SEMI-DETACHED/ROW	290	340	422	520 562	SEMI-DETACHED/ROW	258	308	389	506 559	SEMI-DETACHED/ROW	338	380	456	566 641	SEMI-DETACHED/ROW	326	350	412	461 495
WALKUP	262	310	384	490 552	WALKUP	230	299	351	458 536	WALKUP	262	367	432	541 596	WALKUP	253	342	393	456 476
ELEVATOR 2-4 STY	316	368	464		ELEVATOR 2-4 STY	297	351	441		ELEVATOR 2-4 STY	327	430	485		ELEVATOR 2-4 STY	321	386	445	
ELEVATOR 5+ STY	330	383	477		ELEVATOR 5+ STY	322	377	468		ELEVATOR 5+ STY	361	461	538		ELEVATOR 5+ STY	337	429	492	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: VERNAL, UT NUMBER OF BEDROOMS					MARKET: SIOUX FALLS, SD NUMBER OF BEDROOMS					MARKET: PIERRE, SD NUMBER OF BEDROOMS					MARKET: RAPID CITY, SD NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			554	647 711	DETACHED			479	519 562	DETACHED			489	531 577	DETACHED			513	623 663
SEMI-DETACHED/ROW	338	400	492	617 708	SEMI-DETACHED/ROW	309	351	451	489 534	SEMI-DETACHED/ROW	242	301	396	509 556	SEMI-DETACHED/ROW	319	389	481	592 643
WALKUP	276	366	439	521 588	WALKUP	285	339	413	475 515	WALKUP	236	286	354	482 538	WALKUP	293	366	445	551 612
ELEVATOR 2-4 STY	337	441	478		ELEVATOR 2-4 STY	321	375	442		ELEVATOR 2-4 STY	284	340	442		ELEVATOR 2-4 STY	325	381	481	
ELEVATOR 5+ STY	379	472	527		ELEVATOR 5+ STY	325	375	448		ELEVATOR 5+ STY	309	346	450		ELEVATOR 5+ STY	330	389	486	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: CASPER, WY NUMBER OF BEDROOMS					MARKET: CHEYENNE, WY NUMBER OF BEDROOMS					MARKET: COOY, WY NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			575	696 784	DETACHED			541	588 639	DETACHED			575	696 785
SEMI-DETACHED/ROW	342	390	471	584 667	SEMI-DETACHED/ROW	325	371	447	555 626	SEMI-DETACHED/ROW	342	390	471	584 667
WALKUP	316	355	436	538 616	WALKUP	272	331	412	511 584	WALKUP	316	355	436	538 616
ELEVATOR 2-4 STY	378	430	519		ELEVATOR 2-4 STY	302	374	468		ELEVATOR 2-4 STY	378	430	519	
ELEVATOR 5+ STY	402	454	545		ELEVATOR 5+ STY	313	386	483		ELEVATOR 5+ STY	402	454	545	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

## REGION 9

## HONOLULU, HAWAII AREA OFFICE

MARKET: HONOLULU NUMBER OF BEDROOMS					MARKET: GUAM NUMBER OF BEDROOMS					MARKET: KAUAI NUMBER OF BEDROOMS					MARKET: MAUI NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			801	1042 1184	DETACHED			626	717 805	DETACHED			816	948 1037	DETACHED			737	913 967
SEMI-DETACHED/ROW		564	770	921 1038	SEMI-DETACHED/ROW			507	582 645 760	SEMI-DETACHED/ROW			722	806 938 1026	SEMI-DETACHED/ROW			685	722 902 958
WALKUP	473	543	628	914 1029	WALKUP	342	404	482	548	WALKUP	482	608	648	915 1002	WALKUP	446	576	696	812 867
ELEVATOR 2-4 STY	525	624	655		ELEVATOR 2-4 STY					ELEVATOR 2-4 STY	510	638	677		ELEVATOR 2-4 STY	475	605	726	
ELEVATOR 5+ STY	539	723	891		ELEVATOR 5+ STY					ELEVATOR 5+ STY					ELEVATOR 5+ STY				
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: HILO NUMBER OF BEDROOMS					MARKET: KONA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			574	717 833	DETACHED			703	836 922
SEMI-DETACHED/ROW		484	564	707 823	SEMI-DETACHED/ROW			614	693 825 912
WALKUP	393	435	536	680 802	WALKUP	455	519	605	738 810
ELEVATOR 2-4 STY	424	463	567		ELEVATOR 2-4 STY	483	547	634	
ELEVATOR 5+ STY					ELEVATOR 5+ STY				
MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186			



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REMEDIATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 9

## LOS ANGELES, CALIFORNIA AREA OFFICE

MARKET: LOS ANGELES NUMBER OF BEDROOMS					MARKET: BAKERSFIELD NUMBER OF BEDROOMS					MARKET: SANTA BARBARA NUMBER OF BEDROOMS					MARKET: VENTURA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			768	867 985				606	716 819				768	854 967				725	823 916
SEMI-DETACHED/ROW		615	709	804 922		435	573	679 760			607	738	822 930		535	595	726 791		
WALKUP	470	542	654	779 848	334	410	550	655 711	430	479	619	701 761		460	503	564	691 738		
ELEVATOR 2-4 STY	508	584	705	808 875	351	429	569		447	501	640			481	524	586			
ELEVATOR 5+ STY	639	725	935		501	588	769		581	648	830			626	680	784			
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: PASO ROBLES NUMBER OF BEDROOMS					MARKET: LANCASTER NUMBER OF BEDROOMS					MARKET: OXNARD NUMBER OF BEDROOMS					MARKET: SANTA ANA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			702	783 851				578	666 776				725	824 916				764	924 1006
SEMI-DETACHED/ROW		472	587	705 784		453	546	632 738			535	595	726 791		647	750	907 985		
WALKUP	393	443	546	650 703	354	426	523	604 689	460	503	564	691 738		518	608	699	838 888		
ELEVATOR 2-4 STY	412	483	568		378	450	546		481	524	586			520	626	721			
ELEVATOR 5+ STY	559	624	772		532	608	754		626	680	784			663	781	917			
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			
MARKET: SAN DIEGO NUMBER OF BEDROOMS					MARKET: EL CAJON NUMBER OF BEDROOMS					MARKET: SANTA MARIA NUMBER OF BEDROOMS					MARKET: SAN BERNARDINO NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			639	759 839				639	759 839				652	740 849				581	700 758
SEMI-DETACHED/ROW		516	615	697 817		516	615	697 817			545	622	710 815		478	570	663 772		
WALKUP	416	474	574	673 722	416	474	574	673 722	384	434	503	559 615		406	458	538	637 708		
ELEVATOR 2-4 STY	450	519	626		450	519	626		405	455	524			434	477	558			
ELEVATOR 5+ STY	538	628	768		538	628	768		544	608	719			586	633	758			
MANUFACTURED HOME																			
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186				TRENDED DATE	100186			

## PHOENIX, ARIZONA SERVICE OFFICE

MARKET: PHOENIX NUMBER OF BEDROOMS					MARKET: CASA GRANDE NUMBER OF BEDROOMS					MARKET: FLAGSTAFF NUMBER OF BEDROOMS					MARKET: SAFFORD NUMBER OF BEDROOMS					
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	
STRUCTURE TYPE																				
DETACHED			562	676	765			492	581	650			599	688	770			469	559	627
SEMI-DETACHED/ROW	404	464	555	643	705	331	378	461	542	604	409	456	541	638	725	293	359	442	536	571
WALKUP	386	448	529	619	660	320	373	450	504	559	386	438	529	615	685	251	319	420	498	554
ELEVATOR 2-4 STY	415	476	558			347	400	471			414	466	556			279	347	448		
ELEVATOR 5+ STY	508	580	697								532	589	680							
MANUFACTURED HOME																				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				
TREND DATE	100186				TREND DATE	100186				TREND DATE	100186				TREND DATE	100186				
MARKET: TUCSON NUMBER OF BEDROOMS					MARKET: YUMA NUMBER OF BEDROOMS					MARKET: KINGMAN NUMBER OF BEDROOMS					MARKET: DOUGLAS NUMBER OF BEDROOMS					
-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	-0-	-1-	-2-	-3-	-4+	
STRUCTURE TYPE																				
DETACHED			512	618	672			552	620	711			534	627	719			523	568	679
SEMI-DETACHED/ROW	338	392	477	552	649	361	412	520	584	668	382	420	505	589	675	387	424	494	535	639
WALKUP	319	369	472	537	606	347	394	506	567	638	362	415	495	557	623	359	409	484	520	602
ELEVATOR 2-4 STY	348	398	501			374	421	533			389	442	522			386	436	511		
ELEVATOR 5+ STY	504	568	723								501	560	679							
MANUFACTURED HOME																				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				
TREND DATE	100186				TREND DATE	100186				TREND DATE	100186				TREND DATE	100186				
MARKET: NAGALES NUMBER OF BEDROOMS																				
-0-	-1-	-2-	-3-	-4+																
STRUCTURE TYPE																				
DETACHED			482	568	680															
SEMI-DETACHED/ROW	302	361	444	527	615															
WALKUP	282	343	433	510	588															
ELEVATOR 2-4 STY	304	370	460																	
ELEVATOR 5+ STY																				
MANUFACTURED HOME																				
EFFECTIVE DATE	100184																			
TREND DATE	100186																			



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 9

## SACRAMENTO, CALIFORNIA SERVICE OFFICE

MARKET: SACRAMENTO NUMBER OF BEDROOMS					MARKET: REDDING NUMBER OF BEDROOMS					MARKET: PLACERVILLE NUMBER OF BEDROOMS					MARKET: YREKA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			548	581 667	DETACHED			508	532 610	DETACHED			570	610 700	DETACHED			525	597 660
SEMI-DETACHED/ROW		458	523	575 632	SEMI-DETACHED/ROW		432	478	526 590	SEMI-DETACHED/ROW		480	548	604 664	SEMI-DETACHED/ROW		440	505	585 630
WALKUP	349	415	473	568 632	WALKUP	320	370	429	472 590	WALKUP	360	430	490	597 664	WALKUP	335	395	450	555 615
ELEVATOR 2-4 STY	455	501	557		ELEVATOR 2-4 STY	425	470	520		ELEVATOR 2-4 STY	470	520	575		ELEVATOR 2-4 STY	435	480	530	
ELEVATOR 5+ STY	566	636	718		ELEVATOR 5+ STY					ELEVATOR 5+ STY					ELEVATOR 5+ STY				
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: S. LAKE TAHOE NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			615	712 775
SEMI-DETACHED/ROW		520	595	690 740
WALKUP	395	465	530	634 696
ELEVATOR 2-4 STY	510	565	625	
ELEVATOR 5+ STY				
MANUFACTURED HOME				
EFFECTIVE DATE	100184			
TRENDING DATE	100186			

## SAN FRANCISCO, CALIFORNIA AREA OFFICE

MARKET: SAN FRANCISCO NUMBER OF BEDROOMS					MARKET: FRESNO NUMBER OF BEDROOMS					MARKET: MODESTO NUMBER OF BEDROOMS					MARKET: SAN JOSE NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			1263	1586 1679	DETACHED			539	767 855	DETACHED			449	620 651	DETACHED			904	1053 1114
SEMI-DETACHED/ROW		784	1016	1252 1325	SEMI-DETACHED/ROW		381	491	644 727	SEMI-DETACHED/ROW		349	424	512 565	SEMI-DETACHED/ROW		530	646	783 862
WALKUP	538	622	813	991 1088	WALKUP	321	375	462	590 674	WALKUP	330	349	419	512 565	WALKUP	437	525	624	744 811
ELEVATOR 2-4 STY	592	714	913		ELEVATOR 2-4 STY	402	478	596		ELEVATOR 2-4 STY	426	478	599		ELEVATOR 2-4 STY	468	544	631	
ELEVATOR 5+ STY	752	873	1105		ELEVATOR 5+ STY	601	714	884		ELEVATOR 5+ STY	600	642	783		ELEVATOR 5+ STY	664	760	879	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: OAKLAND NUMBER OF BEDROOMS					MARKET: MARIN NUMBER OF BEDROOMS					MARKET: EUREKA NUMBER OF BEDROOMS					MARKET: SANTA ROSA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			824	966 1009	DETACHED			824	966 1009	DETACHED			530	682 758	DETACHED			783	982 1074
SEMI-DETACHED/ROW		606	771	882 974	SEMI-DETACHED/ROW		606	771	882 974	SEMI-DETACHED/ROW		362	452	663 745	SEMI-DETACHED/ROW		497	613	763 827
WALKUP	498	579	718	813 901	WALKUP	498	579	718	813 901	WALKUP	260	362	427	610 703	WALKUP	426	497	613	763 827
ELEVATOR 2-4 STY	535	586	790		ELEVATOR 2-4 STY	535	586	790		ELEVATOR 2-4 STY	331	438	563		ELEVATOR 2-4 STY	527	614	774	
ELEVATOR 5+ STY	731	799	1039		ELEVATOR 5+ STY	731	799	1039		ELEVATOR 5+ STY	643	770	929		ELEVATOR 5+ STY	704	810	1103	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: SANTA CRUZ NUMBER OF BEDROOMS					MARKET: RENO NUMBER OF BEDROOMS					MARKET: LAS VEGAS NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			669	832 913	DETACHED			643	765 810	DETACHED			680	753 817
SEMI-DETACHED/ROW		452	614	783 863	SEMI-DETACHED/ROW		448	555	692 760	SEMI-DETACHED/ROW		435	557	698 771
WALKUP	380	452	577	744 811	WALKUP	391	448	531	617 684	WALKUP	358	435	552	667 724
ELEVATOR 2-4 STY	468	578	697		ELEVATOR 2-4 STY	503	580	734		ELEVATOR 2-4 STY	472	556	736	
ELEVATOR 5+ STY	608	727	846		ELEVATOR 5+ STY	762	841	1043		ELEVATOR 5+ STY	734	833	998	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

## REGION 10

## ANCHORAGE, ALASKA AREA OFFICE

MARKET: ANCHORAGE NUMBER OF BEDROOMS					MARKET: FAIRBANKS NUMBER OF BEDROOMS					MARKET: JUNEAU NUMBER OF BEDROOMS					MARKET: KETCHIKAN NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			729	806 833	DETACHED			717	782 851	DETACHED			760	866 900	DETACHED			667	760 845
SEMI-DETACHED/ROW		626	698	761 786	SEMI-DETACHED/ROW		614	689	774 835	SEMI-DETACHED/ROW		609	737	825 866	SEMI-DETACHED/ROW		541	636	724 805
WALKUP	435	512	601	711 737	WALKUP	532	586	662	744 819	WALKUP	488	545	678	785 833	WALKUP	419	492	577	659 731
ELEVATOR 2-4 STY	570	671	750		ELEVATOR 2-4 STY	640	760	817		ELEVATOR 2-4 STY	547	618	708		ELEVATOR 2-4 STY	501	572	671	
ELEVATOR 5+ STY	579	682	763		ELEVATOR 5+ STY	650	775	828		ELEVATOR 5+ STY	574	647	737		ELEVATOR 5+ STY	526	582	690	
MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186				TRENDING DATE	100186			

MARKET: BARTER IS. N NUMBER OF BEDROOMS					MARKET: COASTAL AREA NUMBER OF BEDROOMS				
STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+	STRUCTURE TYPE	-0-	-1-	-2-	-3- -4+
DETACHED			1043	1148 1263	DETACHED			1043	1148 1263
SEMI-DETACHED/ROW		920	1013	1115 1226	SEMI-DETACHED/ROW		920	1013	1115 1226
WALKUP	811	893	958	1083 1191	WALKUP	811	893	958	1083 1191
ELEVATOR 2-4 STY					ELEVATOR 2-4 STY				
ELEVATOR 5+ STY					ELEVATOR 5+ STY				
MANUFACTURED HOME					MANUFACTURED HOME				
EFFECTIVE DATE	100184				EFFECTIVE DATE	100184			
TRENDING DATE	100186				TRENDING DATE	100186			



SCHEDULE A- FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION  
(INCLUDING HOUSING FINANCE AND DEVELOPMENT AGENCIES PROGRAMS)

## REGION 10

## PORTLAND, OREGON AREA OFFICE

MARKET: PORTLAND NUMBER OF BEDROOMS						MARKET: BEND NUMBER OF BEDROOMS						MARKET: COOS BAY NUMBER OF BEDROOMS						MARKET: MEDFORD NUMBER OF BEDROOMS						
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	
DETACHED			453	559	606				346	444	496				346	404	450				394	461	516	
SEMI-DETACHED/ROW	290	353	410	499	546		270	313	384	431			267	315	385	428			310	363	413	488		
WALKUP	278	345	397	458	533		197	254	294	363	401		210	255	304	371	416		248	297	338	394	429	
ELEVATOR 2-4 STY	289	357	420				209	272	311				221	267	319				262	309	350			
ELEVATOR 5+ STY	349	414	559																					
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					
MARKET: ONTARIO NUMBER OF BEDROOMS						MARKET: WEST SALEM NUMBER OF BEDROOMS						MARKET: PENDLETON NUMBER OF BEDROOMS						MARKET: BOISE NUMBER OF BEDROOMS						
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	
DETACHED			363	432	482				311	394	435				389	450	505				448	536	576	
SEMI-DETACHED/ROW			269	328	395	438			235	285	367	406			286	358	400	449			325	356	465	512
WALKUP	217	252	312	393	427		187	231	280	357	395		223	273	339	382	420		260	308	350	443	480	
ELEVATOR 2-4 STY	229	270	325				200	247	295				235	285	353				289	318	363			
ELEVATOR 5+ STY							284	351	420										350	415	475			
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					
MARKET: EUGENE NUMBER OF BEDROOMS						MARKET: IDAHO FALLS NUMBER OF BEDROOMS						MARKET: MCCALL NUMBER OF BEDROOMS						MARKET: POCATELLO NUMBER OF BEDROOMS						
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	
DETACHED			365	463	511				324	365	406				361	434	469				375	473	507	
SEMI-DETACHED/ROW			275	348	429	456			242	289	337	379			245	320	386	420			261	367	431	475
WALKUP	215	258	325	400	431		178	225	268	324	365		179	226	302	383	408		196	244	330	391	421	
ELEVATOR 2-4 STY	227	268	338										190	238	326				210	255	347			
ELEVATOR 5+ STY																								
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					
MARKET: TWIN FALLS NUMBER OF BEDROOMS						MARKET: LEWISTON NUMBER OF BEDROOMS						MARKET: COEUR D'ALEN NUMBER OF BEDROOMS												
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+							
DETACHED			353	473	520				325	414	483				363	449	495							
SEMI-DETACHED/ROW			250	312	370	414			246	304	363	421			253	328	383	422						
WALKUP	198	238	301	357	393		192	230	280	347	382		217	232	290	364	396							
ELEVATOR 2-4 STY	213	257	326				223	258	298				239	246	307									
ELEVATOR 5+ STY													324	341	443									
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE						
TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE	100186					TRENDING DATE						

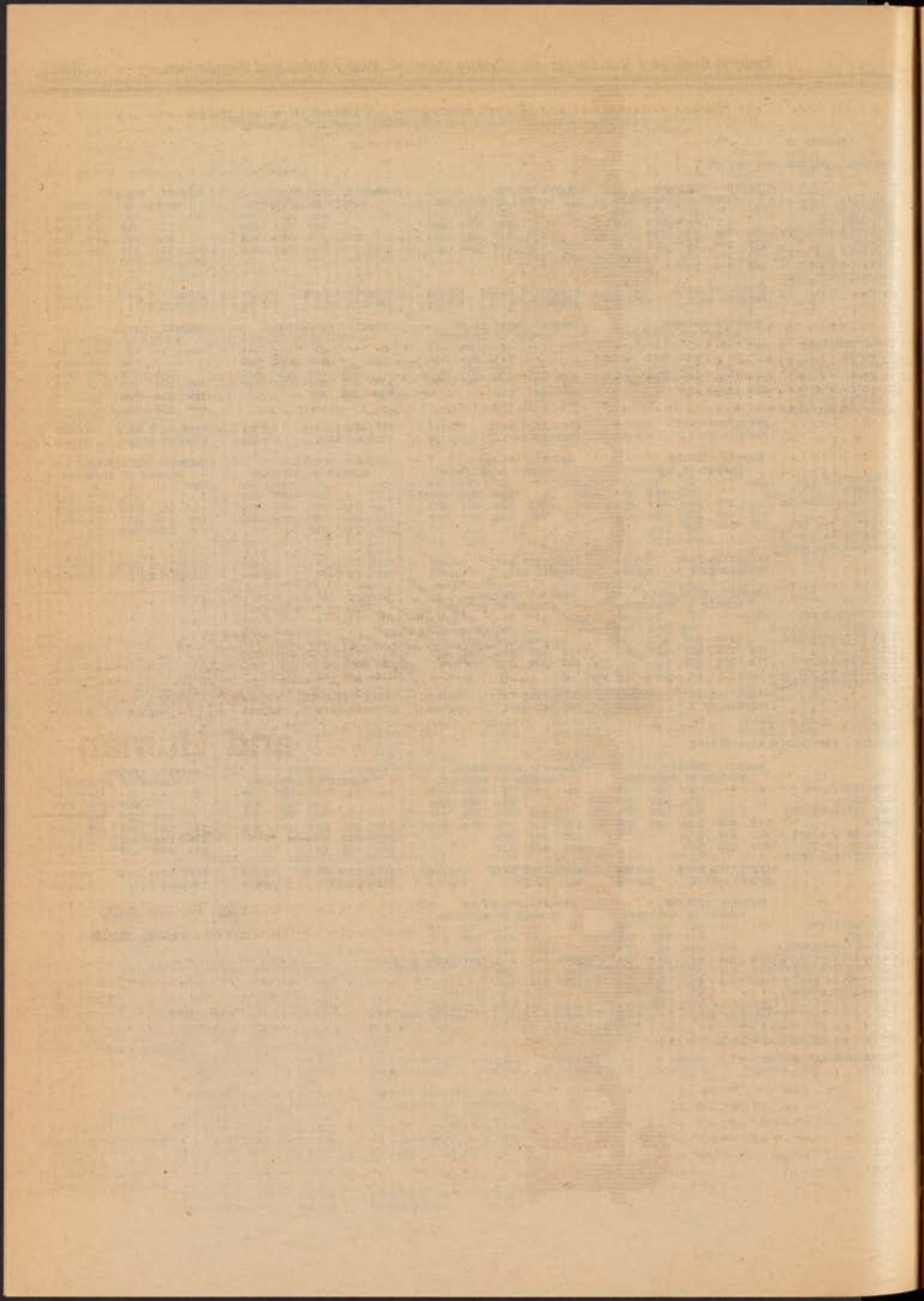
## SEATTLE, WASHINGTON AREA OFFICE

MARKET: SEATTLE						MARKET: BELLINGHAM						MARKET: OLYMPIA						MARKET: YAKIMA						
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						NUMBER OF BEDROOMS						
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	
DETACHED			570	634	758				434	543	586				435	535	657				407	515	589	
SEMI-DETACHED/ROW			407	500	569	674			319	391	475	524			344	392	483	611			329	384	485	548
WALKUP	312	407	500	540	555		238	304	376	459	510		239	305	375	463	533		224	296	346	449	507	
ELEVATOR 2-4 STY	372	418	515				255	321	393				256	322	392				239	312	362			
ELEVATOR 5+ STY	400	500	550				381	456	557				390	458	541				371	444	537			
MANUFACTURED HOME																								
EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					EFFECTIVE DATE	100184					
TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					TRENDED DATE	100186					
MARKET: SPOKANE						MARKET: KENNEWICK																		
NUMBER OF BEDROOMS						NUMBER OF BEDROOMS																		
STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+	STRUCTURE TYPE	-0-	-1-	-2-	-3-	-4+													
DETACHED			429	532	657				420	505	621													
SEMI-DETACHED/ROW			307	404	487	578			267	344	405	470												
WALKUP	230	281	347	431	488		228	254	313	371	435													
ELEVATOR 2-4 STY	246	314	363				268	299	369															
ELEVATOR 5+ STY	380	435	523				327	376	461															
MANUFACTURED HOME																								
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[FR Doc. 85-10039 Filed 4-25-85; 8:45 am]

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# Testis Great Federal Lovers

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Friday  
April 26, 1985

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## Part IV

### Department of Health and Human Services

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Food and Drug Administration

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21 CFR Part 10 et al.

National Environmental Policy Act;  
Policies and Procedures; Final Rule



**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. 79N-0335]****21 CFR Parts 10, 25, 71, 170, 171, 312, 314, 511, 514, 570, 601, 812, 813, and 861****National Environmental Policy Act; Policies and Procedures****AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is setting forth its policies and supplemental procedures for compliance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality's (CEQ) regulations.

**EFFECTIVE DATE:** July 25, 1985. For additional information concerning this effective date, see "Paperwork Reduction Act" appearing in the preamble of this document.

**FOR FURTHER INFORMATION CONTACT:** John C. Matheson, Center for Veterinary Medicine (HFV-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1880.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of December 11, 1979 (44 FR 71742), FDA proposed to revise its rules governing the preparation of environmental impact documents under section 102(2)(C) of the National Environmental Policy Act of 1969. FDA had previously issued regulations (42 FR 19986; April 15, 1977) that responded to guidelines on NEPA issued by CEQ in the Federal Register of August 1, 1973 (38 FR 20550). FDA's 1979 proposal responded, in turn, to CEQ's regulations (40 CFR Parts 1500-1508) published in the Federal Register of November 29, 1978 (43 FR 55978) that were "designed to make the NEPA process more useful to decisionmakers and the public; to reduce paperwork and the accumulation of extraneous background data; and to emphasize real environmental issues and alternatives" (40 CFR 1500.2(b)). The regulations also implemented Executive Order 11514 (March 5, 1970), as amended by Executive Order 11991 (May 24, 1977). CEQ's 1978 regulations required FDA to review its policies, procedures, and regulations to ensure full compliance with CEQ's implementation of NEPA. To achieve this compliance, FDA must revise its regulations in Part 25 (21 CFR Part 25) that implement NEPA.

After consultation with CEQ, FDA published proposed revisions of Part 25 in the Federal Register of December 11, 1979 (44 FR 71742). The agency received comments from 5 trade associations, 10 regulated firms, and 2 other Federal agencies.

**I. Subpart A—General Provisions**

Subpart A states the purposes of the rule, describes FDA's general approach in implementing NEPA and the CEQ regulations, and provides definitions.

**Procedural Issues**

1. Comments objected to FDA's decisions, described in the preamble to the proposal, that: (1) FDA would follow the procedures in the proposal pending publication of the final rule, even though applicants and petitioners were not so obligated; and (2) FDA would not provide a detailed preamble with the proposed rule, because it responds to requirements established by the CEQ regulations. The comments contended that one or both of these decisions violated the Administrative Procedure Act.

FDA disagrees with the comments. FDA concluded that as a Federal agency it was required to follow the CEQ regulations on an interim basis before issuing a final rule. Because, as FDA stated in the proposal, the public was not obligated to comply with the revised procedures until they were published as a final rule, the agency's decision to follow its proposal clearly did not violate the Administrative Procedure Act.

FDA did not publish a detailed preamble with the proposal because the proposed regulation itself was unusually detailed and because many of the changes were required by the CEQ regulations, the provisions of which had been discussed by CEQ in its preamble and regulations and at its public meetings on these regulations. FDA has concluded, nevertheless, that the requests for a detailed preamble, and other comments received, revealed that some of the proposed revisions were unclear. Therefore, this final rule contains a detailed preamble, and FDA has clarified several provisions of the final rule.

**Changes From Previous Regulations**

2. Comments generally expressed a preference for FDA's NEPA regulations now found in Part 25 over the proposed revisions. Several comments contended that the proposal would require excessive paperwork and information. Some comments argued that additional time and money would have to be

expended to comply with the rule as proposed.

FDA believes that the comments misunderstood the proposal. Some comments construed certain proposed provisions to require more information and data than FDA intended. Further, based on its experience with the proposed changes since December 1979, FDA believes that the revisions will reduce the time and resources expended by applicants and petitioners to comply with NEPA with no adverse effects on the environment. Although change may at first be a source of confusion, FDA is confident that the revised regulations will simplify compliance with NEPA.

In revising its environmental regulations, FDA has preserved as many of the substantive provisions of Part 25 as is possible consistent with the CEQ regulations and current environmental impact assessment techniques. (To aid discussion of the new revision, FDA will refer to the regulations now found in Part 25 as "the previous regulations".) Preserving to the extent possible the substantive provisions in the previous regulations benefits applicants and petitioners by providing continuity. FDA has, however, attempted to delete or change provisions which experience has indicated were unnecessary, ambiguous, or unrelated to environmental impact review. FDA has also, in this final rule, rearranged certain regulatory provisions to aid readers interested in finding the provisions applicable to particular FDA-regulated articles.

To implement CEQ's regulations, FDA proposed two significant changes in its NEPA process. First, as required by 40 CFR 1507.3, FDA revised its previous three-level classification of actions subject to environmental review to conform to the two-level classification prescribed by CEQ. Second, FDA replaced the Environmental Impact Analysis Report (EIAR) with an Environmental Assessment (EA). These changes carry out the objective of CEQ's regulations of streamlining the NEPA process by concentrating on environmental issues, eliminating considerations irrelevant to environmental impact assessment, reducing the size and number of NEPA documents, decreasing the time required to prepare and review these documents, and increasing the usefulness of NEPA documents as decisionmaking tools.

Of the three classification levels in FDA's previous regulations, the first environmental review level consisted of actions exempted from environmental review under § 25.1(d). The exemptions were roughly equivalent to the categorical exclusions used in this final



rule, but the previous exemptions lacked the criteria that are now being adopted for exclusions.

The second environmental review level in the previous regulations consisted of classes of actions conditionally exempted from detailed environmental analysis. Conditional exemptions were listed in previous § 25.1(f). Their purpose was to establish large classes of actions in which only limited environmental analyses were required. Information requirements, presented as criteria, were included with most § 25.1(f) actions. The information required to satisfy the criteria varied from extensive to minimal, depending on the class of action involved. The intent of this variation within the conditional exemption group was to permit exemption from the requirement of a full environmental analysis only for those specific actions that resulted in limited environmental introductions due to use of a product that would be marketed as a result of FDA's approval. Additionally, for certain actions FDA required limited information on environmental introductions resulting from the manufacture of the product. A person requesting a conditional exemption was required to prepare a publicly available Statement of Exemption containing all the required information, and the agency prepared a determination that the conditional exemption applied and that the requirements for a Statement of Exemption had been met. Frequently, applicants submitted Statements of Exemption which, after agency review, had to be corrected and resubmitted to be suitable for public display.

The third environmental review level in the previous regulations consisted of classes of actions for which an EIAR was required. The previous EIAR is roughly equivalent to the EA under the CEQ regulations and this final rule.

In the present revision of Part 25, the agency has continued the practice found in previous Part 25 of requiring EA's for all major classes of actions (§ 25.22), unless an action also falls in one of the classes of actions qualifying for a categorical exclusion (§§ 25.23 and 25.24, corresponding to an exemption in the previous regulations, § 25.1 (d) and (f)). Hence, although FDA has conformed to CEQ terminology, it has continued in the revisions the same substantive treatment of most classes of actions that they received in previous Part 25, thus providing continuity for applicants and petitioners. In addition, FDA has granted categorical exclusions to several additional classes of actions that did not enjoy exemptions. These

additional exclusions were based on experience showing that little or no environmental information on product use or manufacture had been required for actions in these classes. FDA could not, however, convert to categorical exclusions the previous conditional exemptions for some of the classes of actions described in previous § 25.1(f) (1) and (3). These classes require more environmental analysis initially because FDA has sometimes had to require additional extensive submissions to fulfill the agency's environmental review responsibilities, and because the agency could neither justify scientifically, nor prepare criteria for, categorical exclusions for all actions within these classes. Although FDA has thus been unable to grant categorical exclusions for these actions, FDA has granted more limited regulatory relief by providing for abbreviated EA's for these actions (final § 25.31(b); proposed § 25.31(e)).

By categorically excluding 10 classes of actions in the previous regulations for which Statements of Exemption previously were required to be submitted (listed in previous § 25.1(f) (2) and (4) through (12)), FDA is sparing many applicants and petitioners the task of first preparing Statements of Exemption and later submitting corrections of any documents found inadequate. The agency also is conserving its resources by reducing the need for repetitive review and evaluation of these documents.

Furthermore, by eliminating the EIAR in favor of the EA, FDA is adopting the approach that experience has shown was clearer to applicants and petitioners. The EIAR format (previous § 25.1(j)) required applicants and petitioners to address such topics as "pollution," "toxic substances," and "human values" without guidance as to when or in what manner these topics were to be addressed. Without intensive case-by-case guidance, applicants and petitioners usually were unable to prepare satisfactory EIAR's. In 1977, the agency began to provide preparers of EIAR's with guidance in the form of an Environmental Impact Operational Directive. The operational directive emphasized how to identify and evaluate potential environmental impacts using information on the product's physical and chemical properties and on the amounts and concentrations of chemical substances expected to be introduced into various compartments of the environment. If the information submitted suggests potential impacts, laboratory screening tests may be indicated unless the scientific literature provides the needed

information. The approach suggested in the operational directive has proved much more successful than the EIAR format in helping applicants and petitioners to prepare adequate EIAR's. Therefore, in the new EA format, FDA has adopted the format of the operational directive rather than that previously used for EIAR's. Applicants and petitioners who have tried the approach suggested in the operational directive will find the new EA procedure quite similar.

Additional changes that will reduce the burden of complying with NEPA, with no adverse effects on the environment, are described elsewhere in this preamble. Among these are a change in § 25.22(c), in response to comments, that reflects current agency practice by specifying that persons who propose to destroy a product that had been recalled at the agency's request or that had been enjoined, seized, or detained in an action initiated by FDA are required to submit an EA or a claim for categorical exclusion only if FDA requests them to do so. The agency is further streamlining this process by first considering, in each case, the information at hand. If this information is sufficient to determine either what the environmental impact is or that a categorical exclusion applies, the person responsible for the product will not be asked to submit an EA or a claim for exclusion.

In another change made in response to comments FDA revised proposed § 25.25 on environmental impact reconsideration of already-approved actions. FDA has concluded that supplements and amendments to already-approved actions need not automatically trigger reconsideration of an original action. The agency will treat a supplement or an amendment as requiring reconsideration of the original action when it has information indicating that there is a need to do so. In addition, in the final rule FDA has revised several proposed requirements in § 25.31a prescribing the format for an EA, partly by tailoring the EA format for industry-initiated actions to omit requirements appropriate only for EA's for FDA-initiated actions. Additional format requirements for agency-initiated actions are specified separately. Also, information requirements relating to the environmental impact of a manufacturing process have been reduced to the items required in the EIAR format in previous § 25.1(j).

In sum, the agency concludes that the revisions made by the final rule will reduce the time and costs associated with the NEPA process, compared both



to FDA's previous regulations and to the proposal, and without a significant increase in the risk of adverse environmental impacts.

FDA encourages industry to consult with the agency before submitting applications or petitions to prevent overlooking applicable categorical exclusions, to obtain guidance in the preparation of EA's and to acquire relevant data. FDA also encourages applicants and petitioners to refer to the scientific literature to obviate unnecessary testing.

3. Nine comments objected that some of the information required in the EA format in proposed § 25.31 duplicated requirements under other Federal, State, and local laws. Three of these comments suggested that, before FDA approves a proposed action, it should obtain from the applicant or petitioner a certification that all EPA regulatory obligations had been met. The suggested procedure would be similar to the conditional exemption process applied to certain of these applications under § 25.1(g)(2) of the previous regulations.

The agency has considered these comments and has concluded that the existence of Federal, State, and local regulation of air and water pollution and of hazardous wastes does not relieve FDA of its independent obligation under NEPA to consider, in its decisionmaking, all relevant environmental effects.

For several reasons, compliance with emissions standards does not satisfy the obligation under NEPA to analyze the environmental effects of a proposed action. First, emissions standards generally apply only to the environmental impacts of production and processing. Because FDA recognizes these impacts as important, the agency requires that any applicable emissions standards be specified in the EA, along with a certification that they are or will be met by the petitioner or applicant. Frequently, however, there are no applicable emissions standards for a new product or chemical subject to FDA approval, in which case certification of compliance with applicable standards would have little meaning.

Second, even assuming compliance with emissions standards that apply to a new chemical, adverse environmental impacts still may occur. In contrast to NEPA's emphasis on environmental impact, as discussed below, emissions standards are often not based solely on this factor. As explained by Cairns, emissions standards are influenced by available treatment technology; the economics of treatment and removal; social factors; and local, State, and national political factors. In sum, emissions standards define

concentrations of emissions for which the environmental and health risks are acceptable to society (Cairns, J., Jr., "Estimating Hazard," *Bioscience*, 30:101-107, 1980).

The term "environmental effects," as defined by CEQ, 40 CFR 1508.8, includes effects not usually addressed by the other Federal, State, or local laws referred to in the comments. CEQ defines "effects" to include "ecological \* \* \*, aesthetic, historic, cultural, economic, social, or health [effects], whether direct, indirect, or cumulative. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial" (40 CFR 1508.8). Thus, mere compliance with emissions standards does not guarantee compliance with the analysis requirement of NEPA, as implemented by CEQ.

Third, emissions standards do not regulate environmental effects of the use or disposal of an FDA-regulated product. These modes of environmental introduction may be significant, even though manufacturing emissions are minor by comparison. For example, one of the primary sources of chlorofluorocarbons entering the stratosphere was from the use of products containing chlorofluorocarbons as aerosol propellants. Assisted by other Federal agencies, FDA prepared an EIS which analyzed the environmental effects of these products. The agency subsequently prohibited the use of chlorofluorocarbons as aerosol propellants based on the health and environmental effects involved. Because emissions standards do not regulate environmental effects of product use or disposal, FDA has required more environmental information in EIA's than would be required only to evaluate the environmental effects of the manufacture of FDA-regulated products.

In sum, a certification that all applicable emissions standards are met by an applicant or petitioner would not cover all the potential environmental effects within the scope of FDA's NEPA review when the agency evaluates chemical entities that are proposed to be marketed for new or additional uses.

4. Other comments discussed the potential for duplication in that EPA regulates products, such as pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and products subject to the Toxic Substances Control Act (TSCA), that also may be subject to FDA requirements.

FDA concedes that the same substance may need to be the subject of

separate environmental effects analyses for EPA and FDA. Although both agencies have worked to eliminate duplication of effort in the environmental impact evaluation of substances regulated by both agencies, applications or petitions submitted to FDA frequently involve a different use of the product than the use(s) reviewed by EPA, and the patterns of environmental introduction often vary. Accordingly, a document done for one agency may not suffice as a NEPA document for the other agency. Furthermore, data filed with EPA under FIFRA and TSCA are often confidential and not available to FDA, while FDA is required by NEPA to make reports to the public on the environmental impact of its proposed actions and to explain how these effects were considered in decisionmaking. FDA has, nevertheless, provided added guidance in § 25.31a(b)(6) on how data developed for EPA registrations can be used to develop the required NEPA documents for FDA. The applicant or petitioner may use these data to analyze the potential environmental impacts of the FDA-regulated use of a product, but must present it to FDA in an EA that can be made publicly available. This approach is similar in purpose to the CEQ regulations (40 CFR 1500.4, 1506.2, and 1506.3) that provide, where appropriate, for the joint preparation or acceptance, or both, of environmental documents by two or more agencies.

5. Two comments contended that FDA should consider environmental impact considerations other than those covered by NEPA. One comment cited regulations of the Advisory Council on Historic Preservation (36 CFR Part 800) which, among other things, explain how a Federal agency's responsibilities under the National Historic Preservation Act of 1966 should be integrated with its NEPA responsibilities. The comment suggested that FDA's final NEPA regulations include a section on the agency's responsibilities under the National Historic Preservation Act. The other comment noted that there was no apparent integration into FDA's proposed NEPA regulations of the many other statutes and executive orders, all listed in the HHS General Administrative Manual implementing NEPA, requiring various environmental impact considerations. The comment asked whether these considerations would be conducted separately.

FDA agrees that the final regulations should describe FDA's responsibility to consider environmental impact under requirements other than NEPA. FDA has added § 25.5 (b) and (c) to the final rule



to clarify the agency's intent that NEPA reviews cover all relevant environmental considerations. Also, the EA formats in § 25.31 now refer to consideration of effects of an agency action on historic places and endangered species as these may be affected by some actions. The applicability of other statutes and executive orders will be considered on a case-by-case basis. It is FDA's policy that, where feasible, all environmental considerations relating to a proposed action shall be included in the required NEPA document.

#### Terminology

Certain proposed definitions have not been included in final § 25.15 because the terms defined are not used in the final rule.

6. Two comments were received regarding the agency's definition of "toxic substance," § 25.15(b)(6), intended solely for use in this rule. Toxic substance was defined in general terms, and a working definition also was provided to aid in determining whether a particular substance is "toxic." One comment suggested that the working definition be deleted, and the other suggested that a single test organism be specified in the working definition.

The agency had considered both of the approaches suggested in the comments when it prepared the proposed definition of "toxic substance." The term is important, because it is used in the criteria for categorical exclusions in § 25.24 and in the requirements for EA's in § 25.31. Because the general definition of the term is informative but lacks the precision needed for determining consistently whether proposed actions are categorically excluded, FDA added the working definition as well. Although it might appear to be more convenient to limit the working definition to a single test organism, doing so would not be as sufficiently comprehensive for predicting environmental effects. The varied physical and chemical characteristics of, and the varied uses of, FDA-regulated products result in enormously varied environmental introductions. Many different organisms may be exposed to these varied introductions. Although comparative toxicology data are now quite limited, they nevertheless suggest that considerable variation exists in the sensitivity of aquatic, terrestrial, and microbial organisms to test chemicals.

Accordingly, FDA has no scientific basis to limit to a single test organism the working definition provided in the definition of "toxic substance." The agency may determine later that a single

test organism can be specified if an adequate comparative toxicology data base has been developed for environmental impact of substances on test organisms.

Therefore, the agency has left essentially unchanged its proposed definition of "toxic substance." The definition provides guidance but leaves flexibility for individual cases.

#### II. Subpart B—Agency Actions Requiring Environmental Consideration

Subpart B discusses agency actions subject to environmental consideration as required in § 1507.3 of the CEQ regulations. The EA and the EIS are the two documents used in this consideration. The shorter EA serves as the basis for FDA's determination of the need for an EIS, which is more detailed.

#### General Procedures

Section 25.20 explains that the environmental consideration procedures in Subpart B apply to all FDA actions not covered by environmental documents prepared under FDA's previous regulations. These actions are individually subject to analyses of their potential environmental effects in an EA or an EIS unless these actions are categorically excluded under § 25.24.

#### Actions Requiring an EIS

Section 25.21 states that there are no classes of agency actions for which it routinely is necessary to prepare an EIS under 40 CFR 1507.3. Section 25.21 is equivalent to § 25.1(a)(1) of FDA's previous regulations. Because the agency could not identify any classes of actions that would routinely require the preparation of an EIS, any determination to prepare an EIS for a proposed action will be based on the case-by-case evaluation of the EA.

#### Actions Requiring an EA

Section 25.22 lists 18 classes of actions that generally require the preparation of an EA in the applicable format described in § 25.31. Individual actions in one of these classes may qualify for categorical exclusion under §§ 25.23 and 25.24, in which case no EA is needed. When submitted, an EA is evaluated by FDA to determine whether an EIS is necessary. After review of the EA, FDA issues either a notice of intent to prepare an EIS or a finding of no significant impact (FONSI), in which case no EIS is required. Section 25.22 corresponds to § 25.1(a)(2) of the previous regulations.

In the final rule, FDA has rearranged the listing of actions requiring an EA, unless categorically excluded, to aid readers interested in finding the

provisions applicable to particular FDA-regulated articles. A cross-reference list for § 25.22(a) of this final rule, with corresponding provisions of the proposed rule and previous Part 25, follows:

Final rule (Section)	Proposed rule (Section)	Previous part 25 (Section)
25.22(a)(1)	25.22(a)(1)	25.1(b)(1)
25.22(a)(2)	25.22(a)(2)	25.1(b)(2)
25.22(a)(3)	25.22(a)(3)	25.1(b)(3)
25.22(a)(4)	25.22(a)(4)	25.1(b)(4)
25.22(a)(5)	25.22(a)(17)	25.1(b)(13)
25.22(a)(6)	25.22(a)(6)	25.1(b)(6), (7)
25.22(a)(7)	25.22(a)(14)	25.1(b)(15)
25.22(a)(8)	25.22(a)(14)	25.1(b)(15)
25.22(a)(9)	25.22(a)(13)	25.1(b)(16)
25.22(a)(10)	25.22(a)(11), (12)	25.1(b)(11), (12)
25.22(a)(11)	25.22(a)(15)	25.1(b)(10)
25.22(a)(12)	25.22(a)(17)	25.1(b)(16)
25.22(a)(13)	25.22(a)(17)	25.1(b)(16)
25.22(a)(14)	25.22(a)(8)	25.1(b)(3), (14)
25.22(a)(15)	25.22(a)(10)	25.1(b)(10)
25.22(a)(16)	25.22(a)(5)	25.1(b)(5)
25.22(a)(17)	25.22(a)(9)	25.1(b)(9), (14)
25.22(a)(18)	25.22(a)(16)	25.1(b)(16)
25.22(a)(19)	25.22(a)(17)	25.1(b)(16)

7. Many comments on proposed § 25.22(a) suggested that certain actions listed as subject to EA's should be categorically excluded. The comments concerned various applications and petitions for FDA's approval to market products under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act. These included approval or issuance of licenses for biological products (three comments), approval of new drug applications (NDA's) and abbreviated new drug applications (ANDA's) (six comments); approval of new animal drug applications (NADA's) and supplements and amendments to NADA's (two comments); approval of requests for certification of new antibiotic drugs (four comments); approval of food additive petitions (one comment); approval of color additives (one comment); withdrawal of approvals of drugs, medical devices, food or color additives, and biological products (one comment); amendments of or exemptions from existing approvals (one comment); and approval of device premarket approval applications or declarations that product development protocols have been completed for medical devices (one comment). A comment suggested a limited EA for certain actions. None of these comments included substantive information to support the suggested blanket eliminations of the EA requirement.

Similar comments were submitted when FDA in 1974 proposed revisions of its environmental regulations (39 FR 13742). The agency concluded then, as it does now after several years of experience, that these classes of actions cannot be categorically excluded from preparation of an EA, which enables



FDA to decide whether an EIS is required. CEQ's regulations require agencies to delineate clearly why actions are excluded from environmental consideration (40 CFR 1507.3). FDA cannot state categorically that all actions in each of these broad classes do not "individually or cumulatively have a significant effect on the human environment" (40 CFR 1508.4). These classes of actions therefore cannot be categorically excluded from the requirement to prepare an EA. FDA has, however, developed criteria for categorical exclusion of specified subsets of many of the actions listed in § 25.22(a). With respect to these subsets of actions, FDA can clearly delineate why environmental impact consideration is not needed, and is granting them categorical exclusions in § 25.24 of the final rule.

8. Two comments suggested that for agency-initiated withdrawal of approvals of drugs, medical devices, food or color additives, and biological products, referred to in proposed § 25.22(a)(13) and final § 25.22(a)(9), the agency, not the sponsor, should prepare the EA.

FDA agrees with the comments. The agency has always prepared and will continue to prepare environmental documents for FDA-initiated actions. A major consideration in EA's on actions to withdraw approval of products is the environmental effects that may be expected as a result of substitute products. Adequate EA's submitted by petitioners and applicants before their products were approved are useful later in determining potential impacts of substitution of some products for others. If adequate EA's were filed for the products proposed for withdrawal or for their substitutes, there is less need for FDA to request manufacturers to submit information or for FDA to undertake its own review of the matter.

9. Section 25.22(b) requires petitioners and applicants who request FDA to take certain actions to prepare and submit an EA with these requests unless the action qualifies for categorical exclusion under §§ 25.23 and 25.24. Section 25.22(b) is substantively the same as that in previous § 25.1(h), as well as the proposal.

10. Section 25.22(c) requires persons proposing to dispose of FDA-regulated products under the conditions described in § 25.22(a)(2) and (3) to prepare and submit an EA with those proposals when requested to do so by the agency. The final rule differs from previous § 25.1(a) and (i) and from the proposal in that an EA is required for dispositions of products only when it is requested in

writing by the agency. This change was made because such persons generally are unaware of NEPA requirements because of the mechanism through which such actions are initiated, i.e., the persons are not seeking approval of products but responding to regulatory actions involving violative products. Because it is generally necessary for FDA to inform these persons of the requirement of an EA, § 25.22(c) codifies the procedure. FDA will not make a written request for an EA without first determining either that an EA is definitely needed for the proposed action or that FDA cannot decide whether a categorical exclusion in § 25.24 applies without additional information.

11. A comment interpreted proposed § 25.22(c) in conjunction with proposed § 25.24(d)(11) (final § 25.24(a)(4)) to mean that EA's will be required for industry-initiated recalls that were not requested by FDA and that such actions would not qualify for categorical exclusion under proposed § 25.24(d)(11).

FDA did not intend this interpretation. Industry-initiated recalls of FDA-regulated products are not considered to be agency actions and, therefore, do not require consideration under NEPA.

12. A comment suggested that a time limitation be added to § 25.22(c) to require that FDA authorize destruction of the affected article within 60 days of the submission of the EA.

The agency concludes that it cannot set a specific time limit, starting with the submission of an EA, by which it will authorize the destruction of a recalled, detained, or enjoined article. The agency is nevertheless committed to the timely completion of the NEPA requirements applicable to such actions. When relatively safe methods of disposition of toxic substances are available, the identification of these methods in an EA and the subsequent preparation of a finding of no significant impact (FONSI) do not normally require 60 days. However, in those cases where no methods are available that would destroy or contain the toxic substance and it is reasonable to expect that significant environmental effects will occur as a result of one or more of the available methods that are being considered, an EIS may be required. Preparation and public review of EIS's normally require more than 60 days.

13. Section 25.22(d) states that the agency is responsible for assuring the accuracy of information contained in an EA, as required by 40 CFR 1506.5(b), and that the agency will decide whether an EIS is needed based on the information in the EA. The responsible agency official then prepares either a Notice of

Intent to prepare an EIS or a FONSI, whichever is appropriate. This paragraph is similar to previous 21 CFR 25.1(m) and is virtually identical to the proposal of this rule.

#### *Procedures for Categorical Exclusions*

14. Section 25.23 describes generally the procedures to be followed for actions that are listed in § 25.24 as categorically excluded from the requirement of an EA. To be eligible for an exclusion, sufficient information about each proposed action must be provided to demonstrate to FDA that the action is within an excluded category and meets the criteria for the applicable categorical exclusion. For FDA-initiated actions, the agency determines whether an action is eligible for categorical exclusion. All of the exemptions and some of the conditional exemptions listed in FDA's previous regulations, 21 CFR 25.1 (d) and (f), have been included as categorical exclusions in the revised regulations. New exclusions also have been added.

15. As mentioned above, some classes of actions that were conditionally exempted in previous §§ 25.2(f) (1) and (3) have not been categorically excluded. FDA's experience has been that considerable environmental data and manufacturing information have been required to obtain conditional exemptions for these classes of actions. Under the previous regulations, this information was provided in a publicly available "Statement of Exemption." However, CEQ's regulation, 40 CFR 1507.3, does not allow agencies to require applicants and petitioners to submit such information to qualify for categorical exclusions. One of the objectives of CEQ's regulations is to reduce paperwork and confusion by requiring consistent use of environmental documents throughout the Federal government (43 FR 55979; November 29, 1978). In addition, FDA lacks the information it would need to exclude those actions formerly covered by the conditional exemptions in §§ 25.1(f) (1) and (3) (see § 25.31a(b) of the final rule). Therefore, for these actions FDA is discontinuing the use of conditional exemptions and Statements of Exemption and is instead providing guidance on the information needed for inclusion in abbreviated EA's. The information needed in these abbreviated EA's focuses on the potential environmental impacts at this site(s) of manufacture and on the use of existing data to assess potential impacts resulting from use of the regulated products. This information is comparable to that needed previously to



apply the criteria for conditional exemptions in previous §§ 25.1(f) (1) and (3) and to provide the manufacturing information required in previous § 25.1(g)(2). The previous conditional exemptions treated as abbreviated EA's in this rule are discussed individually in this preamble in § 25.31a below.

16. One comment suggested that the actions that were conditionally exempted in previous § 25.1(f)(1)(iii) be granted a categorical exclusion in the new regulations. Previous § 25.1(f)(1)(iii) provided a conditional exemption for:

A drug, animal drug, or biological product, which, in chemical structure or biological composition, or known pharmacological properties and indications for use, is identical, similar, or related to a drug, animal drug, or biological product which is already being marketed, and there is no reason to conclude that the marketing of such an additional drug, animal drug or biological product will change the overall use pattern or the existing market for the article involved.

No information was submitted to support this suggestion or to provide for consideration within the categorical exclusion framework of environmental effects due to manufacturing.

The agency concludes that previous § 25.1(f)(1)(iii) will not be incorporated as a categorical exclusion in this rule. The agency has, however, developed categorical exclusions for changes in applications or licenses for previously approved drugs, biological products, and animal drugs (§§ 25.24(c) (1), (2), and (10) and (d)(1), respectively). These categorical exclusions apply to situations in which FDA has previously approved an identical product. For actions that do not qualify for categorical exclusions, § 25.31a provides guidance on the format of the required EA's.

Although the conditional exemption in § 25.1(f)(1)(iii) was intended to reduce environmental consideration by applicants seeking approval to market essentially a duplicate version of a marketed product, the exemption criterion turned out to be too broad, exempting more requested actions than had been intended. A product that was merely similar or related to another product in chemical structure, biological composition, or pharmacological properties and indications for use was eligible for a conditional exemption. Differing interpretations of the terms "similar," "related," and "change in the overall use pattern" resulted in misunderstanding among applicants and petitioners and variability in decisions on requests for conditional exemptions by different agency reviewers. FDA's experience has shown that the agency can justify a categorical exclusion from

environmental considerations only if the product for which approval is sought is essentially identical to a product already being marketed.

17. A comment on § 25.23(c) suggested that an applicant or petitioner should not be required to supply information to establish that a categorical exclusion is applicable to a requested action. It was further suggested that the agency require from applicants and petitioners only a statement that the action contemplated is included within an excluded category and that it meets the criteria for the applicable categorical exclusion.

The agency concludes that submission of only a statement identifying the requested categorical exclusion is sometimes insufficient. CEQ requires both that there be criteria to judge whether an action is excluded (40 CFR 1507.3(b)(2)(ii)), and that the agency be responsible for the accuracy of the information submitted (40 CFR 1506.5). As discussed in § 25.24, many categorical exclusions are for classes of actions that do not result in the introduction of any substance into the environment. Usually, it is self-evident when an individual action belongs to one of these classes and no other information is required. Other exclusions are for classes of actions that do result in environmental introductions. These exclusions contain specific criteria for exclusion which must be met in order for an individual action to be categorically excluded. Therefore, to determine whether criteria for exclusion are met, the agency sometimes requires an applicant or petitioner to submit supporting information. In the cases where it is necessary, the information that must be submitted to show that the criteria for categorical exclusions are satisfied is limited and often has been submitted for other purposes elsewhere in the petition or application. See categorical exclusions under § 25.24 (c) (1) and (2), (d)(1), and (e)(4) for examples where exclusion criteria are based upon information presented elsewhere in petitions and applications.

18. The same comment suggested that the agency should not refuse to accept or file an application or petition solely because the applicant or petitioner fails to specify clearly the provision for categorical exclusion or fails to provide information sufficient to establish that the requested action is subject to a categorical exclusion.

The agency concludes that it will continue its policy, applicable to supporting exemptions under the previous regulations, that failure to include in an application or petition either sufficient information to support a categorical exclusion or an adequate EA

may be sufficient grounds to refuse to accept or file the application or petition. (See previous § 25.1 (g), (h), and (i).) The objective of the provision is to encourage applicants and petitioners to review the potential environmental impacts of their contemplated actions by considering whether an action is categorically excluded or subject to the requirement of an EA before filing the application or petition with FDA. The requirement also assures that any necessary NEPA documentation is submitted at the time the action is first requested, thus preventing unnecessary delays in the agency's evaluation and decision on the contemplated action. Because of the information available to applicants and petitioners, they are in a better position than is FDA to make an initial decision as to the applicability of an exclusion. However, the agency will not automatically refuse to file or approve applications or petitions for failure to claim and support a categorical exclusion that FDA believes is applicable. Such refusals generally will be reserved for those submissions which claim a categorical exclusion but fail to provide sufficient information for the agency to determine whether the claimed exclusion in fact applies.

#### *Listing of Categorical Exclusions*

19. Section 25.24 lists a variety of specific actions that are categorically excluded from the requirement to prepare an EA. The introductory language states the criteria for the exclusions and identifies which of the listed actions are categorically excluded because they generally do not result in the introduction of substances into the environment, which of the listed actions are excluded when they meet specific criteria that are intended to ensure that they will not cause significant environmental effects, and which of the listed actions are excluded because they are routine maintenance or minor construction activities that FDA conducts or contracts for. Certain exclusions listed in the proposed rule (§ 25.24(b) (1), (3), (4), (5), and (8)) are contained in Chapter 30-20-40 B.2. of the HHS General Administration Manual. Therefore, to avoid duplication, these exclusions are not repeated in this final rule.

All previous § 25.1(d) exemptions and most § 25.1(f) conditional exemptions have been redefined as categorical exclusions in this final rule, to conform to CEQ's regulation (40 CFR 1507.3) as explained above in relation to § 25.23. Categorical exclusions differ from FDA's previous § 25.1(d) exemptions in that they are conditional rather than



absolute. Categorical exclusions differ from some of the previous § 25.1(f) conditional exemptions in that no environmental data need be submitted. Further, for all exemptions it was previously necessary to prepare a Statement of Exemption for public review, which is not required for categorical exclusions in this final rule.

In the final rule, FDA has rearranged the listing of categorical exclusions to aid readers interested in finding the provisions applicable to particular FDA-regulated articles. A cross-reference list for § 25.24 of this final rule, with corresponding provisions of the proposed rule and previous Part 25, follows:

Final rule	Proposed rule	Previous part 25 <sup>1</sup>
(a) General		
§ 25.24(a)(1)	§ 25.24(b)(1)	§ 25.1(d) (2), (3)
§ 25.24(a)(2)	§ 25.24(b)(2)	§ 25.1(d)(1)
§ 25.24(a)(3)	§ 25.24(b)(10)	
§ 25.24(a)(4)	§ 25.24(b)(11)	§ 25.1(f)(9)
HHS GAM <sup>2</sup>	§ 25.24(b)(4)	
HHS GAM <sup>2</sup>	§ 25.24(b)(5)	
§ 25.24(a)(5)	§ 25.24(b)(7)	§ 25.1(b)(13)
§ 25.24(a)(6)	§ 25.24(b)(16)	
HHS GAM <sup>2</sup>	§ 25.24(b)(8)	§ 25.1(f)(10)
§ 25.24(a)(7)	§ 25.24(b)(11)	
§ 25.24(a)(8)	§ 25.24(b)(12), (17)	
§ 25.24(a)(9)	§ 25.24(b)(22)	
§ 25.24(a)(10)	§ 25.24(d)(12), (14)	
§ 25.24(a)(11)	§ 25.24(d)(13)	§ 25.1(f)(12)
§ 25.24(a)(12)	§ 25.24(c)	
(b) Foods, food additives, and color additives		
§ 25.24(b)(1)	§ 25.24(b)(13)	§ 25.1(d)(4)
§ 25.24(b)(2)	§ 25.24(d)(15)	
§ 25.24(b)(3)	§ 25.24(d)(5)	§ 25.1(f)(6)
§ 25.24(b)(4)	§ 25.24(b)(14)	§ 25.1(f)(7)
§ 25.24(b)(5)	§ 25.24(b)(6)	
§ 25.24(b)(6)	§ 25.24(b)(15)	
§ 25.24(b)(7)	§ 25.24(d)(6)	
§ 25.24(b)(8)	§ 25.24(d)(7)	
§ 25.24(b)(9)	§ 25.24(d)(4)	§ 25.1(f)(9)
(c) Drugs and biologics		
§ 25.24(c)(1)	§ 25.24(d)(1)	§ 25.1(f)(1)
§ 25.24(c)(2)	§ 25.24 (b)(16), (d)(8)	§ 25.1(f)(1)
§ 25.24(c)(3)	§ 25.24(d)(2)	
§ 25.24(c)(4)	§ 25.24(d)(15)	§ 25.1(d)(5), (f)(11)
§ 25.24(c)(5)	§ 25.24(b)(14)	§ 25.1(f)(7)
§ 25.24(c)(6)	§ 25.24(d)(3)	§ 25.1(f)(4), (5)
§ 25.24(c)(7)	§ 25.24(d)(10)	
§ 25.24(c)(8)	§ 25.24 (b)(16), (d)(1), (3)	
§ 25.24(c)(9)	§ 25.24(d)(2)	
§ 25.24(c)(10)	§ 25.24(d)(10)	§ 25.1(f)(8)
§ 25.24(c)(11)	§ 25.24(b)(21)	§ 25.1(f)(1)
(d) Animal drugs		
§ 25.24(d)(1)	§ 25.24 (b)(16), (d)(1)	§ 25.1(f)(1), (2)
§ 25.24(d)(2)	§ 25.24(b)(18)	§ 25.1(f)(2)
§ 25.24(d)(3)	§ 25.24(d)(2)	
§ 25.24(d)(4)	§ 25.24(d)(15)	§ 25.1 (d)(5), (f)(11)
§ 25.24(d)(5)	§ 25.24(b)(14)	§ 25.1(f)(7)
§ 25.24(d)(6)	§ 25.24(d)(3)	§ 25.1(f)(4), (5)
§ 25.24(d)(7)	§ 25.24(d)(10)	
(e) Devices and radiation products		
§ 25.24(e)(1)	§ 25.24(b)(19)	§ 25.1(d)(6)
§ 25.24(e)(2)	§ 25.24(b)(20)	
§ 25.24(e)(3)	§ 25.24(b)(13)	§ 25.1 (d)(4), (f)(9)
§ 25.24(e)(4)	§ 25.24(d)(1)	

Final rule	Proposed rule	Previous part 25 <sup>1</sup>
§ 25.24(e)(5)	§ 25.24(b)(16)	
§ 25.24(e)(6)	§ 25.24(d)(13)	
§ 25.24(e)(7)	§ 25.24(d)(15)	§ 25.1(d)(5)
§ 25.24(e)(8)		§ 25.1(d)(7)

<sup>1</sup> Provisions in the proposal or previous Part 25 often are related, not identical. Where blanks appear under the headings for previous or proposed rules, no exemption or exclusion previously applied.

<sup>2</sup> HHS General Administration Manual.

Although the categorical exclusions for most of the classes of actions listed in § 25.24 are self-explanatory, several provisions that require an explanation of the action involved, or of the reasons why the criteria for exclusion are usually met, are discussed below.

#### Categorical Exclusions: General

20. Section 25.24(a)(4) (proposed § 25.24(d)(11)) excludes destruction or disposal of articles that have been condemned after seizure, articles whose distribution or use has been enjoined, or articles that have been detained or recalled at agency request. Such actions are excluded provided that the method of destruction or disposition of any articles, including packaging material, will not result in the release of a toxic substance into the environment. This categorical exclusion is a clarification of the conditional exemption in § 25.1(f)(9) of the previous regulations. The categorical exclusion applies to those actions in which the agency may be involved and which may be eligible for exclusion from environmental consideration if the articles destined for destruction or other disposition do not contain toxic substances, e.g., they are contaminated due to decomposition or insect or rodent activity, or are misbranded, and their destruction or other disposition does not otherwise result in the release of a toxic substance into the environment.

21. Section 25.24(a)(8) (proposed § 25.24(b)(12)) was clarified by citing examples of *Federal Register* documents subject to these exclusions. FDA has deleted, as unnecessary, proposed § 25.24(b)(9) which described the exclusion of certain *Federal Register* notices from the requirement of an EA. The notices in question, e.g., notices withdrawing proposed rules and notices of intent to develop regulations or EIS's, do not themselves have environmental consequences.

22. Section 25.24(a)(8) was also revised to refer to amendments to or revocations of procedural regulations, as well as to issuance of such regulations. None of these actions results in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

23. Section 25.24(a)(10) (proposed § 25.24(d)(12) and (14)) excludes the promulgation by the agency of certain current good manufacturing practice (CGMP) regulations or their equivalents and the issuance or denial under these regulations of certain permits, exemptions, variances, or stays. Such actions are excluded if there will be no increase in the quantities or toxicity of wastes entering the environment as a direct or indirect result of the action. Proposed § 25.24(d)(12) included an additional criterion for exclusion: "if there will be no change in the existing uses of the product." This criterion has been deleted from the final rule because CGMP regulations and related actions are not intended to affect the use of regulated products. As described below, the major factor in determining the potential for these actions to have any effect on the environment is whether they would result in increases in the quantities or toxicity of wastes emitted during the manufacture of the regulated product. These actions were not exempted or conditionally exempted from environmental consideration in the previous regulations.

The criteria for exclusion ensure that in-plant changes required by CGMP regulations and their equivalents, e.g., establishment standards for biological products, receive consideration in an EA when the changes result in increased waste flow or increased toxicity of wastes. For example, an action requiring substantial additional water usage or which results in increases in the wastes discharged at a manufacturing facility for certain products does not meet the criteria for exclusion and therefore requires the preparation of an EA. Examination of mitigation procedures or alternatives to the proposed action could result in choice of a final action which conserves water, decreases the concentration of toxic substances present, or otherwise facilitates treatment or reuse of the wastes.

Included in § 25.24(a)(10) is an exclusion from environmental consideration of certain of FDA's good laboratory practice (GLP) regulations. Present GLP regulations (21 CFR Part 58) establish quality control procedures to be used in laboratories conducting clinical tests to be submitted to FDA, usually in support of an application or petition for approval to test or market an FDA-regulated product. GLP's also apply to FDA's own laboratory activities and those of its contractors. GLP regulations are excluded from environmental consideration when they meet the same criteria, discussed above, that establish when CGMP regulations



are excluded from environmental consideration.

24. Section 25.24(a)(11) (proposed § 25.24(d)(13)) excludes the establishment or repeal by regulation of labeling requirements for marketing articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes. This categorical exclusion is a modification of a conditional exemption in the previous regulations (§ 25.1(f)(12)). The modification excludes from environmental consideration all FDA-regulated product labeling that meets the criteria for exclusion.

25. A comment suggested that all labeling requirements established by regulation for marketed articles should be excluded, rather than only the labeling meeting the stated criteria for exclusion discussed in the preceding paragraph. No justification for such a change was provided.

The agency concludes that criteria for exclusion are necessary to determine certain labeling requirements for which preparation of an EA is appropriate. Labeling requirements, including warning labels, may result in market shifts and consequently potentially significant environmental impacts. For example, an FDA requirement for warning labels on aerosol cans using chlorofluorocarbon propellants, which preceded action to ban the use of these propellants, contributed to a shift to uses of substitute propellants. Therefore, an environmental assessment was necessary to determine the potential impacts of the action.

26. Section 25.24(a)(12) (proposed § 25.24(c)) was revised by adding two new provisions, paragraph (a)(16) (v) and (vi), for consistency with the NEPA-implementing procedures of the General Services Administration (45 FR 83; January 2, 1980). With these additions, FDA excludes from environmental consideration the acquisition of occupiable space in existing structures, in addition to the exclusions that were proposed for routine maintenance or minor lease construction activities conducted, or contracted for, by the agency. Actions affecting properties listed or eligible for listing on the National Register of Historical Places do not qualify for categorical exclusion.

#### *Categorical Exclusions: Research*

27. FDA has categorically excluded its actions concerning certain research conducted or supported by the agency (§ 25.24(a)(6), proposed § 25.24(d)(16)) or conducted by applicants or petitioners seeking FDA's approval to investigate food additives (§ 25.24(b)(2)), human drugs, including biologics (§ 25.24(c)(4)),

animal drugs (§ 25.24(d)(4)), and medical devices (§ 25.24(e)(7)). (See proposed § 25.24(d)(15).) These actions are categorically excluded if the wastes generated from the research will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic. By "controlled," the agency means the wastes will be contained, recycled, destroyed, or otherwise treated in a manner that renders them environmentally safe.

FDA actions on investigations of drugs and animal drugs were conditionally exempt under § 25.1(f)(11) of the previous regulations. In the proposed rule, categorical exclusions were continued for these FDA actions and extended to include actions on investigations of medical devices (proposed § 25.24(d)(15)), and research conducted or contracted for by the agency (proposed § 25.24(d)(16)) when these investigations and research meet the criteria for exclusion. In the final rule, § 25.24(b)(2) has been added to exclude FDA actions on the investigational use of food additives for use in human or animal food in the use meets these criteria. With these changes, FDA is applying the same environmental consideration standard to all types of research activities that it conducts, funds, or regulates through prior submission requirements.

28. A comment on proposed § 25.24(d)(15) suggested that no criteria for exclusion were needed because there is no conceivable instance in which an action involving a notice of a claimed investigational exemption for a new drug, new animal drug, or medical device would generate waste that could not be controlled or would be toxic in the amounts released. The comment contended that all such activities should be excluded within limitation, but submitted no information to support this contention.

The agency concludes that only those actions on investigational exemptions that meet the stated criteria for exclusion should be excluded. Although most studies for investigation product development are limited in size, some studies have been very broad in scope. For example, many thousands of animals may be used in the final investigational field studies of animal drugs. The agency agrees with the comment that, in most cases, wastes can be controlled. The criteria for exclusion help ensure that these wastes will, in fact, be controlled by requiring the preparation of an EA if they are not.

#### *Categorical Exclusions: Foods, Food Additives, and Color Additives*

29. Section 25.24(b)(3) (proposed § 25.24(d)(5)) categorically excludes approvals of color additive petitions to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics if data available to FDA do not establish that, at the expected levels of exposure, it may be toxic to organisms in the environment. The final FDA regulations differ from the proposal in that FDA has deleted the proposed additional criterion that, to be eligible for exclusion, a color additive must already be marketed for the petitioned use. This additional criterion was deleted as unnecessary. Although most provisionally listed color additives already are being used in marketed products for the uses requested in petitions for permanent listing, there may be rare cases in which use of a provisionally listed color additive may cease due to termination of provisional listing, only to resume when a decision is on permanent listing. FDA believes that the remaining exclusion criterion in § 25.24(b)(3) will ensure adequate environmental consideration in these rare cases as well as in the more common situation in which there is no interruption in the use of a color additive when it is moved from the provisional list to the permanent list.

Section 25.24(b)(3) provides clearer exclusion criteria than did the conditional exemption in § 25.1(f)(6) of the previous regulations. In deciding whether the permanent listing of a provisionally listed color additive results in release of substances that in the amounts expected to enter the environment may be toxic to organisms in the environment, FDA will consider the petition and other available information, including the scientific literature. If FDA finds that adverse effects are possible, the petitioner will be required to submit an EA.

30. Section 25.24(b)(4) (proposed § 25.24(b)(14)) categorically excludes the testing and certification of batches of color additives. These actions involve the comparison of a specific batch against a standard for an additive for quality control purposes and are not actions to approve the production and marketing of these products. Disposal of small amounts of wastes from FDA laboratories conducting testing and certification activities is considered for potential environmental impact under § 25.22(a)(4).

31. Section 25.24(b)(5) (proposed § 25.24(b)(6)) categorically excludes the



promulgation of an interim food additive regulation. Interim food additive regulations are promulgated under 21 CFR Part 180 for substances having a history of use in food for human consumption or in food-contact surfaces when the safety or functionality of such substances is brought into question by new information that in itself is not conclusive. Such regulation can be issued only when there is reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved. Because an interim food additive regulation provides for the continued use of an already approved substance, such a regulation should be excluded.

32. Section 25.24(b)(6) (proposed § 25.24(b)(15)) categorically excludes establishment of action levels for natural or unavoidable defects in food for humans or animals if these defects present no health hazard. These action levels are established under section 402(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)). It never has been possible to grow, harvest, and process crops that are totally free of natural defects such as insects and insect parts. Action levels represent the limit at which or above which FDA will take legal action against the food to remove it from the market. It is the legal action, rather than the establishment of an action level, that results in any potential for introduction of substances into the environment. Any FDA enforcement of, or action level that results in, the removal of products from the market is considered under §§ 25.22(a) (2) and (3) and 25.24 (a)(4) and (b)(9).

33. Section 25.24(b)(7) (proposed § 25.24(d)(6)) categorically excludes affirmations of a food substance as generally recognized as safe (GRAS) if the substance is already marketed in the United States for the use for which affirmation is sought, and data available to the agency do not establish that the substance may be toxic to organisms in the environment at the expected levels of exposure. Under the previous regulations, GRAS regulations were covered under § 25.1(b)(16), which required a case-by-case determination as to whether an environmental document equivalent to an EA, i.e., an EIAR, was required. Under the new rule, many such actions will be excluded because many GRAS substances meet the exclusion criteria. The agency should have sufficient information in the GRAS petition and the scientific

literature to determine whether the continued marketing of a substance for which GRAS affirmation is sought may, at the expected levels of exposure, result in toxic effects on organisms in the environment.

34. Section 25.24(b)(8) (proposed § 25.24(d)(7)) categorically excludes the promulgation and enforcement of regulations relating to the control of communicable disease or to interstate conveyance sanitation under 21 CFR Parts 1240 and 1250, respectively. Only those actions under Parts 1240 and 1250 that meet certain criteria are excluded.

Part 1240 restricts the interstate shipment of certain animals and articles and establishes requirements for the source and use of potable water on interstate conveyances. The objective of the requirements is to control the spread of communicable diseases. As a result of findings in FDA inspections under these regulations, there may be an enforcement action or voluntary action that results in measures for the control (including treatment, destruction or other disposition) of animals or other articles that are not in compliance with the regulations. If an action involves an endangered species or the release of a toxic substance into the environment, then an EA is required to address considerations under the Endangered Species Act of 1973 or the release of the toxic substance.

Part 1250 establishes requirements for facilities and procedures in conjunction with interstate conveyances to ensure that all food, potable water, and drink served are clean, wholesome, and free from spoilage and that wastes discharged from conveyances are properly handled. FDA enforces these requirements through inspection and may require corrections to be made in conjunction with conveyances before they may continue in interstate commerce. Environmental introductions that result in the release of a toxic substance into the environment require an EA. When proposed as § 25.24(d)(7)(ii), all actions under Part 1250 were excluded. In this final rule, a criterion for exclusion has been added because FDA has determined that some actions taken under this part can result in environmental introductions.

35. Section 25.24(b)(9) (proposed § 25.24(d)(4)) categorically excludes approvals of requests for diversion of adulterated or misbranded food for humans or animal feed to use as animal feed if the disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment. The Federal Food, Drug, and Cosmetic Act prohibits the

sale of products intended as food for humans if the products are adulterated or misbranded. When such products do not contain toxic substances, their diversion to animal feed permits beneficial use of the products and eliminates the need for landfilling, incineration, or some other means of disposal.

#### *Categorical Exclusions: Marketing Approvals*

36. A comment on proposed § 25.24(d) suggested categorical exclusions of all approvals of NDA's, ANDA's, NADA's, and biological product licenses, and any supplements or amendments thereto, providing these do not "significantly affect the quality of the human environment."

FDA cannot adopt this suggestion. CEQ's regulation (40 CFR 1507.3) requires that criteria be established for categorical exclusions. The quoted phrase, which restates the basic NEPA standard, does not satisfy this requirement. Because the agency has no prior knowledge about the environmental impact of new products, excluding all the actions described in proposed § 25.24(d) would make it impossible to distinguish those that have the potential for significant environmental impacts from those that do not. Exclusions have been provided, however, for ANDA's (§ 25.24(c)(1)) and for certain approvals of the types referred to in proposed § 25.24(d), as discussed below on the following provisions of the final regulations: § 25.24(c)(2) (NDA's); § 25.24(c) (8), (10), and (11) (biological product licenses); and § 25.24(d) (1), (2) (NADA's). Certain categorical exclusions for medical device premarket approval applications also are provided in § 25.24(e) (4) and (5).

#### *Categorical Exclusions: Human Drugs and Biological Products*

37. FDA has added a categorical exclusion for approvals of ANDA's in § 25.24(c)(1). Although ANDA's have been specifically mentioned in the conditional exemption in § 25.1(f)(1) of the previous regulations, they were not specifically mentioned in the proposal. Approvals of ANDA's are categorically excluded because they merely allow on the market generic equivalents of drugs that already have been approved and thus do not change the levels of substances entering the environment. These actions are similar to approvals for supplements and amendments to NADA's for which the proposed exclusion, § 25.24(d)(1), applied.



Therefore, the same criteria for exclusion are applied to ANDA's.

38. FDA has broadened the categorical exclusion in § 25.24(c)(2) (proposed § 25.24(b)(16) and (d)(18)), for approvals of certain amendments or supplements to NDA's. The proposal would have excluded only amendments and supplements seeking certain types of labeling and packaging changes not requiring prior approval.

FDA has categorically excluded all approvals of changes not requiring prior approval described in § 314.70(c) and (d), as well as other approvals of amendments or supplements to NDA's, in those cases where the stated criteria are met; that is, the proposed approval provides that the drug will not be administered at higher dosages, for longer duration, or for different indications than were previously in effect.

39. Section 25.24(c)(3) (proposed § 25.24(d)(2)) categorically excludes withdrawals of approvals of NDA's and ANDA's when the drug is no longer being marketed or at the request of the application holder. These actions are not subject to other criteria for exclusion because withdrawals of this type involve discontinued products or products with such small sales that their withdrawals do not result in environmental introductions of substitute drugs.

40. Section 25.24(c)(5) (proposed § 25.24(b)(14)) categorically excludes the testing and certification of batches of antibiotics and insulin. Testing and certification of antibiotics and insulin are excluded for the reasons given in paragraph 30 above.

Although FDA has issued regulations (47 FR 39155; September 7, 1982) exempting all antibiotic drugs and antibiotic-susceptibility devices from certification, these regulations provide for reimposition of testing certification where necessary, and the statute allows manufacturers to request certification even if FDA does not require it. Hence, it still is appropriate to provide in § 25.24(c)(5) a categorical exclusion for antibiotic testing and certification.

41. Section 25.24(c)(6) (proposed § 25.24(d)(9)) categorically excludes the promulgation of a monograph for a "not new" drug, antibiotic drug, or over-the-counter (OTC) drug if the drug is already marketed for the proposed use and data available to the agency do not establish that the drug may be toxic to organisms in the environment. The criteria in the final regulations are less restrictive and more appropriate for monograph rulemaking than were those in the proposal. The proposal would have excluded promulgation of a drug

monograph only if "the proposed monograph will not permit the article to be administered at higher dosage levels, for longer duration, or for significantly different indications than were previously in effect."

FDA has deleted a reference to monograph regulations for in vitro diagnostic products because of the revocation, in the *Federal Register* of February 1, 1980 (45 FR 7474), of the procedures for promulgating such regulations. Because in vitro diagnostic products are medical devices, standards for them may be issued under the procedures in 21 CFR Part 861 for medical device performance standards, and the categorical exclusion in § 25.24(e)(3) of these regulations would exclude such standards from environmental consideration if the applicable criteria are met.

Promulgation of drug monographs was conditionally exempt under § 25.1(f) (4) and (5) of FDA's previous regulations.

42. A comment asserted that all OTC drug monographs should be excluded from environmental consideration, whether or not they met the proposed exclusion criteria. The comment argued that OTC drugs are chemicals of such "low volume" that they will seldom be present in the environment at concentrations high enough to have any significant environmental effects.

The agency concludes that promulgation of drug monographs may cause changes in the levels at which substances are introduced into the environment and that some of these substances may be bioactive at low concentrations. Therefore, criteria are needed to identify those monographs for which an EA must be prepared. As discussed in the preceding paragraph, the criteria for exclusion in the final regulation are less restrictive than those in the proposal, and will exclude more OTC drug monographs. Furthermore, because the ingredients used in products regulated by monographs are already being marketed and often have been for many years, the agency generally will have sufficient information about the product, in the administrative record of the monograph proceeding and from the scientific literature, to identify any substances to be controlled by a monograph that are toxic to organisms in the environment.

43. FDA has added to the final regulations a provision (§ 25.24(c)(7)) that categorically excludes establishment of bioequivalence requirements for marketed drug products if there is no change in the existing levels of use or intended uses of the products. Bioequivalence requirements, which may be imposed by

regulation under 21 CFR 320.1, are established to ensure uniformity among different brands of pharmaceutical products containing the identical therapeutic moiety intended for the same indications. Requirements that affect the levels of use of a product or the intended use of a product might change the amounts or types of wastes entering the environment due to production, use, or disposal of the product or its substitutes. Regulations establishing bioequivalence requirements generally have no effect on the dosage levels or the indications for which the drug products are approved.

Although bioequivalence requirements were neither exempt nor conditionally exempt under FDA's previous regulations, a categorical exclusion of these requirements is consistent with other categorical exclusions, e.g., the exclusion in proposed § 25.24(d)(10) of the issuance of additional standards for a licensed biological product if there is no change in the existing levels of use or intended uses of the products.

44. FDA has added to the final regulations a provision (§ 25.24(c)(8)) that categorically excludes actions on changes reported under 21 CFR 601.12 in biological product or establishment licenses. This categorical exclusion is consistent with other exclusions for actions on certain changes in NDA's (§ 25.24(c)(2)(i), proposed § 25.24(b)(16)) and in NADA's (§ 25.24(d)(1)). In all these cases, the changes have no effect on the environment because they do not result in changes in the environmental introduction of previously approved products.

45. FDA has revised § 25.24(c)(10) (proposed § 25.24(d)(10)) to exclude any biological product standard regulation that meets the exclusion criteria, rather than simply the promulgation of "additional" standards for such products under 21 CFR Parts 620 through 680, as was proposed. Thus, standards for groups of biologic products and general standards, such as those promulgated under 21 CFR 600.16 and Part 610, are categorically excluded if they meet the exclusion criteria.

#### *Animal Drugs*

46. Section 25.24(d)(1) categorically excludes NADA's or supplemental NADA's for a previously approved animal drug if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the drug



may be toxic to organisms in the environment.

47. A comment argued that excluding an animal drug to be marketed under the same conditions of approval as a previously approved animal drug is inappropriate because this approach gives the new competitor an undue advantage over the original developer.

The agency concludes that considerations of competitive advantages between the original and subsequent manufacturers do not justify the imposition of unnecessary requirements that are not justified by NEPA.

48. Two comments suggested that FDA grant categorical exclusions for FDA approvals of new animal drugs in medicated feed blocks and of new animal drugs in liquid feed supplements.

The agency cannot adopt this suggestion because approvals of these types are likely to lead to the release of substances into the environment. However, certain approvals may be eligible for exclusion under § 25.24(d), e.g., if the approval involves a previously approved new animal drug.

49. Several categorical exclusions concerning actions on animal drugs, § 25.24(d) (3) through (7), correspond to similar exclusions for human drugs in § 25.24(c) (3) through (7).

#### *Devices and Radiation Products*

50. FDA has broadened the categorical exclusion in § 25.24(e)(2) (proposed § 25.24(b)(20)) to cover device classification under section 513 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 860 as well as reclassification. In any case in which classification or reclassification changes the marketing status of the device, such as by requiring premarket approval, other provisions of the regulations, e.g., §§ 25.22(a)(18) and 25.24(e) (4) and (5), govern when environmental consideration must occur.

51. A comment suggested the categorical exclusion of approvals of device premarket approval applications (PMA's) and of notices of completion of product development protocols (PDP's) for medical devices.

The agency concludes that, in general, an EA must be required in applications seeking premarket approval of medical devices, just as the agency requires EA's in similar applications for other new products it regulates. However, these applications are excluded under § 25.24(e)(4) if the subject device is of the same type and for the same use as a previously approved device and if approval of the device does not result in the release of substances that could cause toxic effects on organisms in the

environment. Devices that are excluded by this provision compete for the same market with already approved devices of the same type and use and therefore do not result in increased environmental introduction of the device.

52. FDA has added a provision (§ 25.24(e)(5)) that categorically excludes changes in a PMA or notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice. This addition corresponds to the exclusion in § 25.24(c)(2) of certain changes in NDA's.

53. FDA also added, in § 25.24(e)(6), a categorical exclusion of a restricted device regulation issued under section 520(e) of the Federal Food, Drug, and Cosmetic Act when the action will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

#### *Retroactive Environmental Consideration*

54. Section 25.25 discusses when FDA will conduct a retroactive environmental review of existing regulations, approvals, or other actions. The proposed section was similar to § 25.1(c) of the previous regulations. Proposed § 25.25(a) stated that an amendment, supplement, or exemption proposed for an existing regulation or approval (§§ 25.21 through 25.24) which had not previously received environmental analysis would trigger retroactive review of the existing regulation or approval when such consideration was determined to be necessary to assess the environmental effects of the amendment, supplement, or exemption. Proposed § 25.25(b) also provided that environmental review would also be necessary for actions that had not previously received environmental analysis after new information was made available to the agency suggesting that potentially significant environmental effects may be occurring.

55. Three comments opposed any retroactive environmental consideration that would require EA's for FDS-regulated products already being marketed. A fourth comment suggested that retroactive environmental review should be conducted only as provided for in proposed § 25.25(b), i.e., where new information comes before the agency that suggests the need for such reconsideration.

Although FDA cannot adopt the approach suggested by the three comments, it agrees with the fourth comment. In any case in which retroactive review of an action is deemed necessary, there will probably

be information before the agency suggesting that potentially significant environmental impacts may be occurring. Accordingly, the agency concludes that proposed § 25.25(a) is unnecessary and had deleted this paragraph from the final rule. Proposed § 25.25(b), which is now § 25.25(a), states that retroactive consideration of existing regulations, approvals, or other actions is triggered only by new information indicating such need. The agency has no plans for systematic retroactive review of the environmental impact of existing regulations, approvals, and actions. Nevertheless, the agency has the responsibility to reconsider and revise any such past decisions, in certain cases as part of a general reconsideration of a decision and in others when it learns that environmental problems may have resulted from such a prior decision.

#### *III. Subpart C—Preparation of Environmental Documents*

Subpart C describes the content and format of environmental assessments (EA's) (§ 25.31), findings of no significant impact (FONSI's) (§ 25.32), notices of intent to prepare environmental impact statements (EIS's) (§ 25.33), and EIS's (§ 25.34). The only category of document formats in which FDA received significant comments was that for EA's.

#### *EA Format*

56. FDA presented a single EA format in proposed § 25.31(b) and provided in proposed § 25.31(e) for abbreviated versions of several format items for certain actions. In the final regulations, FDA has developed five separate EA formats as follows: Format 1—Proposed approvals of FDA-regulated products; Format 2—Withdrawals of approval and other restrictions; Format 3—Grants, extramural contracts, and other research agreements; Format 4—Establishment of tolerances or action levels; and Format 5—Destruction of condemned, enjoined, detained, or recalled articles. In addition, FDA is providing abbreviated versions of Format 1 for six types of proposed approvals in which environmental concerns are more limited than in other approvals subject to the usual EA format requirements. Most of the actions eligible for abbreviated versions of Format 1 were the subject of conditional exemptions under previous § 25.1 (f) and (g), but did not qualify for conversion to categorical exclusions because information had to be submitted to determine whether the actions would have significant environmental effects. The various



formats in the final rule are similar to the proposed format as modified by proposed § 25.31(e), and as further revised in response to comments as described below.

57. FDA received many comments on the proposed EA format. As discussed above in paragraph 2, the comments contended that the format would result in additional paperwork, delays, and costs. Specific objections to the EA format included: (1) that FDA had so significantly expanded the EIA requirements in previous § 25.1(j) that the new EA requirements would approach, equal, or exceed the requirements for an EIS; (2) that the proposed EA requirements would not result in useful information; and (3) that technology to address some proposed EA requirements is unavailable.

As explained above in paragraph 2, FDA believes that many of these comments misinterpreted the proposed requirements. The EA format differs from the previous EIA format in describing a systematic approach to environmental review of proposed actions to approve the marketing of chemicals. The EIA had presented only a list of general topic areas like "Pollution" and "Toxic Substances" to be addressed. The EA format presents formally in regulations an effective approach to environmental review that FDA has used since 1977 in preparing its own EIA's and in guiding applicants and petitioners using its Environmental Impact Operational Directive (also discussed in paragraph 2 above). Experience has proven that the previous approach of simply providing a list of general topics to be addressed without giving specific accompanying directions often led to the preparation and submission of inadequate environmental documents. The agency then frequently could not accept the documents and had to provide case-by-case guidance on how to correct the documents' deficiencies. The agency seeks to reduce the delay that results from these corrections, consultations, and resubmissions by providing in EA formats a more comprehensive and systematic approach to environmental impact consideration that will yield better results. The additional formats described in the preceding paragraph will assist in these efforts.

FDA recognizes that efforts to predict environmental effects must deal with many uncertainties, some due to limitations of existing technology. To keep track of environmental testing methodology, the agency monitors and evaluates methods developed by the joint committee publishing *Standard*

*Methods* (APHA, Standard Methods for the Examination of Water and Wastewater, 15th Ed., American Public Health Association, Washington, DC, pp. 1134, 1981), EPA, the Organization for Economic Cooperation and Development (OECD), American Society for Testing and Materials (ASTM), and the Society for Environmental Toxicology and Chemistry (SETAC) in addition to reports in the general scientific literature. FDA endorses the efforts of these organizations to seek efficient and economical procedures to predict the environmental impacts of chemicals before they are released into the environment. The agency also continues to offer timely review of environmental testing programs and protocols proposed by applicants and petitioners in preparing EA's as well as written guidance on environmental data acquisition. When technology is absent, or it is infeasible to obtain definitive data to satisfy a given format requirement, FDA accepts the use of predictions developed from calculations or estimates based on available data.

FDA endorses a tiered or step-sequenced scheme for acquiring environmental data in which the first screening tests done are the most simple and generalized, with more complex and detailed tests reserved for chemicals identified by screening as having a potential for adverse effects. Many such schemes are available in the scientific literature (references are available from the contact person listed above). Applications and petitioners are encouraged to choose a scheme for acquiring environmental data that is appropriate for their research and development processes so that they may obtain needed environmental impact data without undue delay and expense.

58. A comment suggested that FDA adopt to the extent possible the premanufacturing notice (PMN) form created by EPA for submission of environmental and other data under section 5 of the Toxic Substances Control Act.

The agency concludes that applicants and petitioners may use PMN forms to organize and summarize environmental data, as described for items 14 and 15 of § 25.31(a), but not as substitutes for EA's. PMN's involve only the submission of data and do not include the analysis of data that is necessary for NEPA documents.

59. Two comments suggested that FDA delete from the EA format the proposed requirement to consider environmental impacts at the sites of production. The comments claimed that the requirement would duplicate other

Federal, State, and local emissions requirements. A third comment suggested that the EA consider impacts only at the sites of production and claimed that these impacts are the only ones that the manufacturer can control.

The agency concludes that it can fulfill its responsibilities under NEPA only by requiring an applicant or petitioner that proposes to market an FDA-regulated product to ascertain carefully, in a public document, the environmental impacts of FDA's approval of the product at the sites of production, during the product's use, and with its disposal. But FDA has decided (as discussed below in paragraph 62) to rely principally on certification of compliance with applicable emissions requirements, along with identification of emissions, in assessing impacts at the sites of production.

FDA acknowledges that neither the preparers nor reviewers of EA's can determine precisely the potential environmental impacts of substances introduced into the environment as a result of the production, use, and disposal of the product permitted by the proposed action. These introductions need not, and indeed often cannot, be measured directly because the FDA-regulated product may not be currently present in the human environment. However, metabolism and excretion data, data on the migration of chemical substances from a packaging material into foods, and information on the potential market for the product frequently are known. Information of this type should be used to make the best possible estimate of the environmental introductions that might occur from use and disposal of the FDA-regulated product. Although many substances may be introduced into the environment at the site of production, usually only the product and its metabolic products and degradative residues, if any, are expected to enter the environment through use and disposal.

60. Two comments objected that socio-economic factors are not considered in the EA process. The previous EIA format, § 25.1(j)D.9., required a risk-benefit analysis to determine whether the economic benefits to the public of the proposed action outweighed the action's potential risks to the environment.

CEQ regulations state that "economic or social effects are not intended by themselves to require preparation of an environmental impact statement. When an environmental impact statement is prepared and economic or social and



natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects \* \* \* (40 CFR 1508.14). The agency interprets this provision to mean that these effects do not have to be considered in determining whether an EIS is required for a particular action. It would be an unnecessary burden upon the agency and upon applicants and petitioners to have to address socio-economic factors in EA's, which merely provide the basis for the agency's determination whether to prepare and EIS or FONSI. Therefore, in the EA formats in the final rule, the only risk-benefit analysis required is to consider the environmental benefits and risks of the proposed action, and of the alternatives when consideration of alternatives is required.

#### EA's for Proposed Product Approvals: Format 1

61. Section 25.31a(a) prescribes a format for nonexcluded, industry-initiated requests for approval of food and color additives, affirmations of food substances as generally recognized as safe (GRAS), human drugs, biological products, animal drugs, and class III medical devices. In some cases, not all items in the format may apply. Preparers of EA's for such cases should contact an individual designated to handle NEPA questions in the FDA center handling the application or petition and agree on a different format for that individual case. The contact person listed above can provide the names of such individuals. Furthermore, the amounts and kinds of information will vary on a case-by-case basis.

FDA is presenting a basic format in § 25.31a(a), followed by formats in § 25.31a(b) in which certain items are abbreviated for certain classes of actions. In this preamble, FDA is discussing only those format items that require explanations or that were the subject of comments. The following chart shows how the format items in Format 1 of the final regulations correspond to EA format items in the proposal and to EIR format items in the previous regulations:

Final § 25.31a(a)	Proposed § 25.31(a)	Previous § 25.1(j)
Item 1	Item 1	Item A
Item 2	Item 2	Item B
Item 3	Item 3	Item C
Item 4	Item 4	Item D.1
Item 5	Item 4	Item D.1
Item 6	Item 5	Item D.2 a, b, c
Item 7	Item 6	Item D.2 a
Item 8	Item 7	Item D.2 a
Item 9	Item 8	Item D.2 a, D.6
Item 10	Item 10	Item D.2 b
Item 11	Item 11	Item D.4
Item 12	Item 12	

Final § 25.31a(a)	Proposed § 25.31(a)	Previous § 25.1(j)
Item 13	Item 13	Item E
Item 14	Item 14	Item D.2 d
Item 15	Item 15	Item D.2 d

62. A comment on proposed format item 5 suggested that in light of EPA, State, and local regulation of emissions, FDA need not require estimates of quantities, concentrations, and durations of emissions at sites of production. The comment suggested that FDA continue to follow the practice in its previous regulations, § 25.1(j), of simply requiring certification of compliance with applicable emissions controls.

FDA has revised the regulations in response to the comment. FDA has decided to continue its previous practice of reliance on certification of compliance with emissions requirements, coupled with identification of emitted substances sufficient to allow the location in the scientific literature of data on the substances and closely related chemicals. Based on the identification of, and literature about, the emitted substances, FDA can determine whether it needs more information about the potential environmental impacts of the emissions, e.g., quantities, concentrations, and duration of emissions. Such additional information generally will not be needed.

Accordingly, in the final regulations FDA has revised proposed format item 5 as format items 5 and 6. Format item 5 requires identification of the chemical substances that are the subject of the proposed action. Format item 6 requires identification of the substances emitted at the sites of production; a citation of, and statement of compliance with, applicable emissions requirements; and a discussion of how the approval of the proposed action would affect this compliance.

63. Format item 7 (proposed item 6) requires consideration of the fate of substances identified in item 6 that are introduced into the environment as a consequence of product use and/or disposal. When an FDA-regulated product or its potentially harmful byproducts, constituents, derivatives, or metabolites are released into the environment through use or disposal of the product, it is important to determine the potential for these introduced substances to be transported among, transformed by, and accumulated in various "environmental compartments," e.g., air, water, soils, and organisms.

A reasonable, state-of-the-art approach for predicting the probable

fate of chemicals introduced into the environment is a step-sequenced combination of physical/chemical characterizations and simple laboratory tests that help define the chemicals' potential for degradation, transport, transformation, and accumulation. The mobility and potential accumulation of a chemical in the environment can be estimated from various physical/chemical measures that are obtained quickly and economically in the laboratory. Some of the more important measures predictive of environmental mobility and distribution are *n*-octanol to water partition coefficient, vapor pressure, water solubility, dissociation constant(s), and soil sorption/desorption isotherm.

Chemicals in the environment may be transformed by either of two means: (1) Biodegradation and (2) chemical transformations, including photochemical reactions. For FDA-regulated products that are meant to be ingested by humans or target animals, information is frequently already available on the pharmacokinetics and metabolism of the product. These pharmacokinetic and metabolic patterns, when considered with the structure of the chemical, are useful in predicting the occurrence of biologically mediated transformations in the environment. Mobility and accumulation data are used to determine whether the chemical is retained in biologically active environmental compartments long enough for biological transformations to take place. If biodegradation appears likely, one of a number of available biodegradation laboratory screening procedures can be chosen to determine the rate and extent of degradation that occurs.

Chemical degradation through hydrolysis may be important for organic chemicals with hydrolyzable functional groups, e.g., esters, amides, alkyl halides, epoxides, and phosphoric esters. Oxidation due to reactions with free radicals in the atmosphere or in water may be important routes of chemical transformations, depending on the transport of the chemical into these environments. When an organic chemical absorbs light in the ultraviolet range of the ultraviolet-visible spectrum, this fact is an indication that photolysis in air or water may occur.

64. A comment stated that models to supply environmental fate information have not yet been developed for all chemicals and that, for FDA-regulated products, data are scarce on photochemical reactions, rain-out, leaching, and sorption to soils and sediments.



The agency's approach described above does not necessitate use of holistic environmental fate models, but rather allows extrapolations by recognized methods from physical/chemical laboratory data to actual situations. Upon request, FDA will provide applicants and petitioners with specific, technical guidance on these extrapolation techniques.

65. Five comments concerned the definition of the term "worst case" that was included in proposed format item 7. They questioned whether the term includes catastrophic natural events, e.g., fires, floods, etc., and whether technology is available to make "worst case" predictions, and asserted that the costs of such predictions would be astronomical.

The agency did not intend that the term "worst case" include catastrophic natural events. To avoid confusions, FDA has deleted from the final rule the term worst case analyses. The agency intends that, for FDA-regulated products, the maximum potential environmental introductions due to normal use and/or normal disposal of the products affected by proposed actions be predicted.

Prediction of the fate of substances introduced into the environment nearly always contains elements of uncertainty. When these predictions are made in EA's, preparers of EA's should make conservative estimates in the areas of uncertainty.

Further guidance is available in CEQ's regulation, 40 CFR 1502.22, on incomplete or unavailable information.

66. A comment suggested that the term "ecosystem" should be defined more specifically and narrowly, but did not make any specific suggestions.

The agency concludes that the term "ecosystem" need not be redefined in this regulation. The scope of review of the fate of chemical substances released into the environment will depend on the extent to which the material is transported among various environmental compartments. Although some chemicals may have global effects, e.g., chlorofluorocarbon aerosol propellants, most others have effects limited to the localities where they are introduced, e.g., rapidly degrading or nonmobile substances.

67. Three comments suggested that FDA set ground rules which provide that where the concentration of an environmentally significant substance emitted into an ecosystem can reasonably be predicted to be below the detection capabilities of scientifically or economically feasible analytical methods, then FDA would, for that ecosystem, waive the required

predictions of the substance's fate and effects.

The agency believes that the approach described above might well be acceptable, if the EA thoroughly discusses the method used to predict the environmental concentration of the substance, the assumptions made, and the areas of uncertainty, including limitations of analytical test methods or other technology. Furthermore, the method used to make the prediction must be reasonable considering what is known of the physical/chemical characteristics of the substance and the pattern of its production, use, and/or disposal.

68. Format item 8 (proposed item 7) requires that preparers of EA's predict, where applicable, effects on animals, plants, humans, and other organisms and effects at the ecosystem level, using the information presented in items 6 and 7 on the introduction and fate of substances together with relevant toxicological data or other appropriate methods.

FDA interprets section 105 of NEPA to supplement, not duplicate, consideration of effects on humans required by the Federal Food, Drug, and Cosmetic Act and the other health protection statutes it administers. Therefore, consideration of effects on humans is normally addressed through cross-references to actions being taken by FDA under health protection legislation. In addition, occupational exposure to FDA-regulated products may be addressed by cross-references to actions taken in response to requirements established by the Occupational Safety and Health Administration, except that occupational exposure requirements may not exist for new FDA-regulated products.

Effects of chemicals on animals, plants, and other organisms often cannot be predicted without knowledge of the toxicological data showing the concentrations of chemicals or substances at which effects are expected to occur. The types of data required for these predictions obviously vary with each chemical evaluated. When introduction and fate data indicate that a chemical is not transported into a particular environmental compartment or that initially low concentrations degrade rapidly into simple, commonly occurring derivatives, there is little or no need for toxicological data for life in that compartment, and item 8 would consist of a prediction that no harmful effects are likely to occur. If a product's production, use, or disposal will cause intermittent introductions of short-lived chemicals, item 8 would usually be

limited to acute effects. If a product's production, use, or disposal will cause continuous introductions of short-lived chemicals, or continuous or intermittent introductions of long-lived chemicals, item 8 should address chronic effects and ecosystem-level effects.

The requirement in item 8 to use any relevant toxicological data includes data already required, for the application or petition, e.g., to show the effectiveness or human or animal safety of the product under the applicable statutory requirements. The same toxicological data may be used to discuss the effects of the environmental residues on, as applicable, microorganisms and nontarget animals. In addition, applicants and petitioners will find that the general scientific literature often contains data applicable to organisms in environmental compartments exposed to FDA-regulated products or to potentially harmful chemicals resulting from the products' production, use, or disposal. In some instances, applicants or petitioners may have to obtain new data needed to predict effects on exposed environmental compartments.

69. Three comments suggested that in items 6, 7, and 8 of the EA format, FDA should confine its attention to the introduction, fate, and effects of new chemicals and of chemicals reasonably expected to have a significant impact on the environment.

The regulations are structured so that most EA's will concern new chemicals or chemicals that may have significant effects. Many of the regulations' categorical exclusions recognize that the agency already has adequate information about most products that are already in the environment to exclude actions on these products from environmental consideration. Even if an action on an already marketed chemical is not categorically excluded, an EA for such an action should not be difficult to prepare because much of the information required for an EA would be readily available.

70. As discussed above in paragraph 5, FDA had modified item 9 to require specification of any effects of the proposed action on historic places and endangered species.

71. Three comments on proposed item 8 stated that because applications and petitions to FDA would be filed considerably in advance of engineering and construction of required facilities, applicants and petitioners could only approximate the natural resources (land, minerals, and energy) required to produce, transport, use, or dispose of a given amount of the product.



FDA agrees with the comments, but must retain this item to fulfill its responsibilities under NEPA. Because uncertainty may well exist in these areas, especially at the time applications and petitions are filed, the level of uncertainty in making estimates and approximations in item 9 should be discussed.

72. The three comments also suggested that some level of significance be established below which requirements for information and data on energy/resource utilization would be waived. One of these comments suggested that FDA set the significance level cut-off for energy at 250 million BTU's/hr and the significance level cut-off for raw material at 10 million kilograms/yr.

FDA believes the suggestion of a threshold significance level for energy and raw materials has merit. FDA will consider applying such levels in its implementation of these regulations, once scientifically supportable threshold levels are developed. FDA lacks the support that it would need to adopt the specific cut-offs suggested in the latter comment described above.

73. Two comments specifically addressed proposed format item 9, which would have required preparers of EA's to discuss disruptions of the physical environment (noise, odors, and traffic congestion) that would be associated directly or indirectly with a proposed action. Both comments suggested such disruptions are normally handled by State and local authorities who are better qualified than a Federal agency to evaluate the impact of these disruptions. These comments recommended that proposed item 9 therefore be deleted or modified so that certain actions were excluded from this requirement. A third comment stated that such information could only be estimated for many proposed actions.

The agency has deleted this item because actions on FDA-regulated products rarely cause physical disruptions of the types described.

74. Format item 10 requires preparers of EA's to describe measures taken to avoid or mitigate any identified potential adverse environmental impacts associated with the proposed action. FDA is interested in information on the mitigation of adverse environmental effects even if the effects being mitigated are not "significant" within the meaning of NEPA. Effective mitigations of proposed actions' adverse environmental effects, even significant effects, can, however, avoid the need for an EIS.

75. A comment questioned the proposed requirement to consider

"potential" adverse environmental effects in item 10 on mitigation measures and in item 11 on alternatives. The comment suggested that the word "actual" be substituted.

The agency believes that the use of the word "potential" is appropriate because of the uncertainties associated with the prediction of environmental effects when applications and petitions are filed. Even the best calculations, estimates, and studies can predict only potential environmental effects, and with varying levels of uncertainty, before substances enter the environment.

76. Two comments objected to the proposed requirement in format item 12 of a listing of persons preparing the assessment, their qualifications, and persons and agencies consulted and their areas of expertise.

The agency believes that it needs to know who prepared EA's and their qualifications. The requirement is analogous to one in CEQ's regulations (40 CFR 1502.17) that requires such information from preparers of EIS's. Having this information simplifies the task of obtaining answers to questions about procedures and data described in EA's and thus facilitates the agency's review of EA's.

77. A comment suggested that the required reference list in item 14 and appendices in item 15 be modified to allow reference to data in applications and petitions.

Although the agency concludes that items 14 and 15 should remain in the EA format, the agency does not object to the use of cross-references to submissions found in other parts of an application or petition.

When the data are confidential and cannot be appended, summaries of the data may satisfy item 15, with references made to the sections of the application or petition where the data are found.

78. The same comment suggested that, alternatively or additionally, FDA should exempt from items 14 and 15 any action that has no adverse environmental impact.

FDA cannot adopt this suggestion because references and appended studies support the conclusion that a proposed action has or does not have a potential for significant environmental effects.

79. Several comments on proposed § 25.31 (c), (d), and (e) interpreted these provisions as expanding significantly the information requirements in EA's. Proposed § 25.31(c) encouraged the use of existing information in satisfying the information requirements for EA's. Proposed § 25.31(d) encouraged those

who prepared EA's to address, to the extent possible, impacts associated with the products' entire production-use-disposal cycle and to use existing scientific and engineering literature in predicting potential environmental effects. Proposed § 25.31(e) provided guidance for applicants, petitioners, and agency preparers on how to abbreviate EA's for certain classes of action. This guidance appears in the final rule in § 25.31a(b) and formats 2 and 3 (§§ 25.31b and 25.31c).

FDA believes it obvious, from the comments, that the agency's intent in proposing these provisions was misunderstood. Paragraphs (c) and (d) of proposed § 25.31 were intended to assist preparers of EA's by informing them of methods of obtaining required information and were not requirements. Section 25.31(e) reduced EA requirements for certain actions.

To avoid the confusion reflected by the comments, FDA has deleted proposed § 25.31 (c), (d), and (e). Much of the guidance found in these proposed provisions is now found in the specialized formats for EA's included in this final rule. Section 25.31(c) as found in this final rule now contains provision for incorporation by reference from other available public documents.

#### *Abbreviated EA, Format 1—Certain Food Additive Approvals*

80. Section 25.31a(b)(1) (proposed § 25.31(e)(2); previous § 25.1(f)(1)(v)) permits abbreviated EA's for nonexcluded proposed approvals of food additives that are present in finished food-packaging material, at no greater than 5 percent by weight, for either of two reasons: because they are used in the production of and become nonfunctional components of the finished food-packaging material, or because they are intentionally added in small quantities to improve the properties of the finished food-packaging material.

Previous § 25.1(f)(1)(v) and proposed § 25.31(e)(2) used the term "minor constituents in food-packaging materials" to refer to food additives that are present in food packaging at low levels and therefore have reduced potential for causing significant environmental impacts. These terms are not used in the final rule in order to avoid confusion with the term "constituent" used in FDA's advance notice of proposed rulemaking (47 FR 14464), which concerns a policy for regulating carcinogenic chemicals in food and color additives.

FDA cannot categorically exclude these approvals consistent with CEQ's



definition (40 CFR 1508.4) and guidance. Rather, an EA is needed to assure consideration of: (1) the environmental impacts of the food additives at the sites of their production; (2) the environmental impacts of the food additives at the sites of production of food-packaging material; (3) environmental impacts of the food additives at the site of disposal of the food-packaging material; and (4) any increases in the consumption of natural resources and energy resulting from the approval of the food additives.

81. Two comments stated that requiring an abbreviated EA for these types of food additives was an unnecessary burden that would not serve a useful purpose and argued for retention of the requirements of previous § 25.1(f)(1)(v). Both comments perceived the proposed abbreviated EA requirement as expanding greatly the environmental impact information necessary to support these types of food additive petitions.

FDA believes that, with certain changes made in response to comments, the environmental information required for these food additives is basically the same as information required to support Statements of Exemption under the previous regulations.

Under the previous regulations, petitioners were required to demonstrate that the food additive and the packaging material in which the food additive would become a component met criteria designed to ensure that approval of the petition would: (1) not create new markets for or affect the environmental impact of the disposal of the packaging material, and (2) not result in the replacement of a substance already in use with one that is not chemically or toxicologically similar. In addition, information on the environmental impact of the manufacture of the food additive was required to be submitted in a Statement of Exemption along with information relating to the criteria for exemption.

Frequently, petitioners have had to submit additional information to enable the agency to reach a conclusion about whether the action qualified for an exemption. For example, although the concentration of these food additives in the food-packaging material may be small, the market volume for these articles may be large. Consequently, a petitioner often had to supplement the Statement of Exemption by estimating the concentration of the food additive entering the environment at the site of disposal of the food-packaging material and by considering this estimate in light of toxicity information. In some cases, additional toxicity studies were

required. Other examples of food additives for which additional information has often been requested are preservatives used in the production of food-packaging material that become nonfunctional components of finished food-packaging material. Because such a substance is not a functional component of finished food-packaging material and efforts are made to prevent the preservative from becoming a component of finished food-packaging material, it is quite possible for the preservative to enter the environment at the site of production of the food-packaging material, with resulting potential for toxicity to aquatic organisms or for other adverse environmental effects. In these cases, petitioners were requested to estimate the concentration of the substance entering the environment at the site of production of the food-packaging material and to consider this estimate in light of the concentrations shown by toxicology data to produce harm. Mitigations of adverse environmental effects, such as warning labels on the product, were sometimes necessary.

Thus, the information required in the Statement of Exemption, along with any supplemental information usually requested, was not substantially different from that required in the proposed EA format, as abbreviated by proposed § 25.31(e)(2), with two exceptions. First, the proposed abbreviated assessment contained a reduced requirement, in that petitioners no longer had to show that a proposed additive was intended to replace a chemically or toxicologically similar substance already in use but had, instead, to provide information on whether a proposed additive was for the same use as another additive already in use. Second, the proposed abbreviated EA format required some additional information not required in the previous regulations. Specifically, additional information was required to assess the environmental impact of manufacture of the food additive, and petitioners had to address each item in the full EA format.

FDA has made the following changes in the final format, after considering the comments on the proposal:

(1) The information required to access the environmental impact of production of the food additives has been reduced and is now basically the same as that required under the previous regulations.

(2) Specific guidance informs petitioners how to make predictions on whether the food additives will enter the environment in quantities that will produce toxic effects.

(3) Petitioners ordinarily need not provide documentation on format item 9,

utilization of resources and energy, if the proposed food additive is intended for the same use as another additive already in use. Food additives intended to replace other additives having the same use are expected to have comparable energy requirements and will not materially change the potential uses of the packaging material to which they are added.

(4) Less information is required about food additives that are present as functional components of finished food-packaging material than is required about those food additives that are used in the production of food-packaging material and become nonfunctional components of finished food-packaging material. As explained above, the latter type of food additive is more apt to enter the environment at sites of production of food-packaging material of which it is a component due to efforts to prevent the food additive from becoming a component of finished food-packaging material.

(5) Format items 7 and 8 encourage petitioners to rely on existing data in the petition, which may be incorporated by reference, or in the scientific literature in satisfying EA requirements. This guidance should discourage unnecessary testing merely to satisfy the EA requirements.

82. In § 25.31a(b)(2), FDA is providing an abbreviated version of format 1 for nonexcluded proposed approvals of food additives used as components of food-contact surfaces of permanent and semi-permanent equipment or of other food-contact articles intended for repeated use. These additives often have limited market volume. Environmental impact at the site of production of the additives is normally the major environmental concern.

Section 25.1(f)(3) of FDA's previous regulations provided a conditional exemption for food additives to be used as components of food-contact surfaces of permanent or semi-permanent equipment or of other food-contact articles intended for repeated use. Petitioners had to show that the food additive that was the subject of the petition belonged to one of the exempted classes of items, a fact that was nearly always evident from the petition. Also, they had to submit information on the environmental effects of the production of the proposed food additives, as described in previous § 25.1(g), in a Statement of Exemption. The criteria for exemption and information required were relatively straightforward and were not the subject of varying degrees of interpretation.



In § 25.31(e)(3) of the proposed rule, FDA added an information requirement concerning environmental effects at the sites of disposal. In certain instances, environmental introductions of chemicals might occur at the sites of disposal due to leaching of chemicals from food-contact articles. Food additive petitions ordinarily include data on the migration of chemicals from the food-contact articles as part of the showing of safety, and FDA believes that these data can be used to estimate the environmental concentrations that might be present due to the disposal of the food-contact articles.

83. A comment objected to the proposal to require an EA for this class of actions, arguing that such a requirement would increase significantly from the previous regulation the information required and thus the time, paperwork, and costs involved. The comment preferred the conditional exemption under § 25.1(f)(3) of the previous regulations.

The agency acknowledges that the proposed regulations would require additional information not required by the previous regulation, such as additional information on the environmental impact of the production of the food additive and of the disposal of the food-contact article containing the food additive. Also, FDA proposed to require petitioners to address each item of the EA format.

The agency could not, however, develop previous § 25.1(f)(3) into a categorical exclusion. To assess the environmental impact of manufacture of the food additive and disposal of the food-contact article containing the food additive, FDA needs the kind of information that, under CEQ's regulations, is more appropriately included in an EA. However, because FDA recognizes that it needs much less information for the environmental review of these petitions than it does for other FDA actions, the agency has in the final rule reduced the information requirements so that they are virtually identical to those under the previous regulations.

FDA is providing a special abbreviated format for these food additive petitions, based on proposed § 25.31(e)(3), but with the following changes:

- (1) Information required to assess the environmental impact of production of the food additive had been reduced.
- (2) To determine the potential environmental impact of the food additive resulting from environmental introductions due to the disposal of food-contact articles containing the proposed additive, petitioners are

required to estimate the maximum potential yearly market volume for the proposed food additive.

(3) Documentation for format items 7 through 11 and item 15 is ordinarily not required.

#### *Abbreviated EA Format 1—Certain Human Drug and Biological Product Approvals*

84. Section 25.31a(b)(3) provides an abbreviated version of format 1 for nonexcluded proposed approvals of NDA's for human drugs and biological product license applications for products intended for use in the prevention, treatment, or diagnosis of a rare disease, or for a similarly infrequent use; for ophthalmic or topical drug or biological product applications; or for local or general anesthetic drugs. These products ordinarily have limited distribution and use. Environmental impact at the site of production is the principal environmental concern with these relatively low-volume products.

Previous § 25.1(f)(1)(i) provided a conditional exemption for a drug, animal drug, or biological product intended for use in the prevention, diagnosis, or treatment of a rare disease, for infrequent use, or for use in insignificant amounts (taking into account projected effects on animals or humans). Applicants were required to submit a Statement of Exemption demonstrating that the product for which they were requesting action met one of the criteria addressing the frequency of product use and including data on the environmental effects of the manufacturing process for the product.

85. Four comments requested that the previous § 25.1(f)(1)(i) conditional exemption be converted into a categorical exclusion in the new environmental regulations, but did not suggest any clearer criteria for exclusion. Nor did these comments provide justification for eliminating the past requirement for data relating to the environmental effects of the manufacturing process. The basis for one of these comments was that the costs involved in preparing an abbreviated EA, as described in the proposed rule, would greatly reduce any incentive a sponsor might have for the development of these products, most of which provide minimum economic return.

The agency concludes that it cannot develop previous § 25.1(f)(1)(i) into a categorical exclusion. Requested actions of this type which cannot meet other categorical exclusions require the preparation of an abbreviated EA.

As described in the preceding paragraph, FDA encountered difficulties

in applying the terms in the previous regulations, and applicants expended considerable efforts attempting to show that they qualified for exemption. These problems would continue with any categorical exclusion. Moreover, FDA cannot satisfy its responsibilities under NEPA without requiring submission of environmental data on these proposed approvals. As discussed elsewhere in this preamble, CEQ's regulations on categorical exclusions do not allow agencies to require such data submissions by those seeking exclusions.

Although FDA is not providing a categorical exclusion for these approvals, it is limiting the information required to be included in an EA. As in proposed § 25.31(e)(4), requirements for information on a product's introduction, fate, and effects were limited to the consideration of the environmental impact of the manufacture of the product and to the determination of environmental concentrations of the product, its metabolites, and the degradation products resulting from the use of the product. Environmental introductions from the use of the product were to be estimated based upon knowledge of the frequency of use, mode of administration, and availability of the product. Furthermore, in codifying proposed § 25.31(e)(4) in the final rule's abbreviated format at § 25.31a(b)(3), FDA is making the following revisions to clarify the information required to show the limited use of these types of products, and to make the requirements comparable with those under the previous regulations.

(1) Information required for format item 6 to assess the environmental impact of production of the product is basically the same as that required under the previous regulations.

(2) Information to assess the potential environmental impact resulting from the use of the product is limited to estimating the potential yearly market volume for the product.

(3) Information is ordinarily not required for format items 7 through 11 and item 15.

#### *Abbreviated EA Format 1—Certain New Animal Drug Approvals*

86. Section 25.31a(b)(4) provides an abbreviated EA format for nonexcluded proposed approvals of new animal drug applications and supplements and amendments to such NADA's for animal drugs intended for use under prescription or veterinarian's order; for treatment of a disease occurring in minor species animals, as defined in 21 CFR 514.1(d); for use in nonfood



animals; for ophthalmic or topical application; or for local or general anesthesia. These drugs have limited production and use due to their intended uses or availability, or both. Therefore, approvals of these drug products generally result in limited environmental introductions of substances compared with other animal drug approvals.

87. Five comments suggested that the actions in question be categorically excluded from the requirement of an EA.

FDA cannot adopt this suggestion because it needs information on the possible environmental effects of these animal drug product approvals at the sites of production. FDA also needs information to judge whether the environmental introductions that result from use of these products have the potential to cause significant environmental effects.

Although the comments presented information on the density of domestic nonfood animals in rural and urban areas of the United States, they did not explain how FDA could avoid evaluation of environmental effects of the drugs' production. Indeed, the information submitted shows that the total number of nonfood animals treated with drug products may be considerable and that the market volume for such products may be large. This information thus supports the need for the agency to evaluate manufacturing impacts in its decisionmaking, because environmental introductions would be concentrated at no more than a few production sites rather than distributed in small amounts over a relatively large area.

Even though these actions were conditionally exempt from an EIA under previous § 25.1(f)(1)(ii) due to their limited potential for environmental effects from use or disposal, FDA recognized when it created the exemption that the drugs' production could have environmental effects. Thus, applicants not only had to demonstrate in a Statement of Exemption that the animal drug met the specified criteria for exemption, but also had to submit environmental information on the manufacturing impacts of the product.

Although the previous conditional exemption was sound in theory, FDA found it difficult to apply. There were frequent cases in which actions met the criteria for exemption, but nevertheless were clearly high-volume drugs of wide availability intended to be used frequently in large populations of animals, with consequent large and potentially significant environmental introductions. For example: (1) technological developments have made it economically feasible for some drugs to be administered individually to all

members of herds or flocks of food-producing animals; (2) drugs are frequently changed slightly by target animal metabolism, but still are excreted as bioactive compounds; and (3) drugs for prevention of diseases and parasites in nonfood animals, e.g., prevention of heartworm in dogs, may be administered frequently or continuously to a very large proportion of the nonfood animal population. When such cases arose, FDA had to interpret the terms "limited number," "significant quantities," "pharmacological use," and "individual dose administration" in light of the original intent of the conditional exemption. Attempting to follow both NEPA and FDA's conditional exemption regulation thus became an unnecessarily long and complicated process.

In summary, FDA found that the conditional exemptions in previous § 25.1(f)(1)(ii) were excessively broad in that the criteria for exemption frequently exempted drug products that were not intended to be exempt. Accordingly, in preparing the proposed rule, FDA determined that those actions subject to this previous conditional exemption could not be developed into categorical exclusions due to the difficulties with the criteria cited above, as well as to the continued need to examine the environmental impacts from manufacture of such drug products. FDA instead provided, in proposed § 25.31(e), that these actions would be subject to an abbreviated EA requirement concentrating on potential impacts at the site of the product's manufacture and on the use of existing data to assess potential impacts resulting from the product's use.

FDA has codified proposed § 25.31(e)(1) in an abbreviated format at § 25.31a(b)(4). The final regulations do not permit the use of this format in three circumstances in which, under the previous regulations, applicants qualified for conditional exemptions.

First, previous § 25.31(f)(1)(ii) conditionally exempted approvals of animal drugs for pharmacological use in animals which metabolize the drug so that no significant quantities of the drug are excreted into the environment; in proposed § 25.31(e) and final § 25.31a(b)(4), FDA did not make these approvals eligible for abbreviated EA's. Rather, these approvals will be handled by the full EA format (Format 1), when the approvals do not belong to any other category that is abbreviated. Even Format 1, however, allows omission of unnecessary information. Based on FDA's experience evaluating environmental documents on animal drug approvals, the agency believes that a showing that a drug or any other FDA-

regulated product is not excreted as the parent compound or as bioactive metabolites normally precludes the need to assess further the environmental fate and effects of the compound's use, whether or not the drug is for pharmacological use. Thus, approvals where there is such a showing self-limit the information required for environmental assessment even when the full EA format is used.

Second, in § 25.31a(b)(4) of the final rule, FDA has replaced the phrase "treatment of a disease" in proposed § 25.31(e)(1) with a clearer and more limited term, "treatment of a disease occurring in minor species animals, as defined in 21 CFR 514.1(d)." The proposal would have broadened the criterion in previous § 25.1(f)(1)(ii), which conditionally exempted animal drugs for pharmacological use in the treatment of a disease or condition which requires individual dose administration. At the time of the proposal, FDA believed that the abbreviated information requested in the EA on potential environmental introductions resulting from the use of such a drug would be sufficient for the agency to determine whether the EA needed to be supplemented with information on environmental fate and effects. This proposed provision promised to save time and paperwork for persons requesting approval of animal drugs for treatment of diseases that occur infrequently, that occur in animal species with small populations in the United States, or that are administered in confined conditions. In developing the final rule, however, FDA decided that the provision would probably mislead some applicants for approval of high-volume, frequently used drugs into thinking that they need not submit information on the environmental fate and effects of use and disposal of the drugs. Delays in FDA's consideration of the application could result when, after FDA had reviewed an EA that lacked such information, the agency informed the applicant of the need to acquire and submit further environmental information. NADA's for drugs to be used in the treatment of animals that are not minor species and that do not belong to any other abbreviated category should include an EA in the full format described in § 25.31a(a). Special attention, however, should be given to the provisions for omitting unnecessary information, using existing information, and consulting with FDA's environmental staff, as discussed above.

Third, FDA has deleted reference to approvals of new animal drugs that are



in vitro diagnostics because such products are now devices, under a revised definition of "device" enacted in 1976 (21 U.S.C. 321(h), Pub. L. 94-295), and are no longer subject to premarket approval requirements.

In addition to the changes described above, FDA has made the following changes in response to comments on the proposed action:

(1) Information required to assess the environmental impact of production of the product is basically the same as was required by the previous regulation.

(2) Information on the environmental introduction of the drug product is limited to an estimate of the maximum yearly market volume. Other information on the introduction, fate, effects, and natural resource use of the drug product associated with its use is not normally required. EA format items 7 through 11 and item 15 are therefore not ordinarily completed for such products. When the estimated maximum yearly market volume and expected use pattern suggest the potential for environmental effects due to the use of the product, FDA will require further specific information to address these format items.

#### *Abbreviated EA Format 1—Substances That Occur Naturally in the Environment*

88. Section 25.31a(b)(5) provides for abbreviated EA's for nonexcluded proposed approvals of FDA-regulated substances that occur naturally in the environment. Environmental concerns about such products ordinarily are limited to effects at sites of production.

Previous § 25.1(f)(1)(iv) provided a conditional exemption from an EIR for approvals of FDA-regulated products that met all of the following criteria:

(1) The article is composed of a substance or its derivatives that occur naturally in the environment and that may reasonably be considered to be nontoxic in the amounts used;

(2) The article is not metabolized in its use and is excreted unchanged back into the environment or, if it is metabolized, the metabolites in the amounts excreted into the environment are naturally occurring in the environment or may reasonably be considered to be nontoxic; and

(3) The use of the article can reasonably be expected on the basis of all available evidence not to alter significantly the prevalence and/or distribution in the environment of the substance or its derivatives or their metabolites.

Applicants and petitioners had to demonstrate that their product met all the above criteria for exemption and to

submit a Statement of Exemption that provided information on the environmental effects of the manufacturing process. Consequently, FDA included in the proposed rule a provision for abbreviation of EA's for proposed approvals of substances occurring naturally in the environment (proposed § 25.31(e)(6)), using wording similar to that in previous § 25.1(f)(1)(iv).

89. A comment said that the language in proposed § 25.31(e)(6) was ambiguous and subject to wide differences in interpretation.

FDA agrees with the comment. For clarity, FDA has codified proposed § 25.31(e)(6) in the final rule as an EA format at § 25.31a(b)(5). In addition, FDA has clarified information required to assess the environmental impact of production of the product and limited it to that required under the previous regulations.

#### *Abbreviated EA Format 1—Products Regulated by EPA*

90. Section 25.31a(b)(6) (proposed § 25.31(e)(8)) provides for abbreviated EA's for nonexcluded proposed approvals of FDA-regulated products that have been registered with EPA as pesticides for other uses or have been considered by EPA under section 4 or 5 of the Toxic Substances Control Act. Abbreviated EA's for such products are justified because they have already been screened for environmental fate and effects as a result of satisfying EPA's requirements for the EPA-regulated uses. As discussed in paragraph 4 above, FDA has tried to avoid duplicating the environmental review carried out by EPA under other statutes.

FDA has made the following revisions in the final rule:

(1) The scope of actions eligible for this abbreviated EA has been broadened to include proposed FDA approvals of products regulated by EPA whether or not the EPA-regulated use is similar to the proposed use regulated by FDA. This change was made because it was determined that at least some of the environmental data submitted to EPA in support of an EPA-regulated use of a product should aid also in evaluating the potential environmental impact of a different FDA-regulated use of the same product.

(2) Because FDA-regulated uses are usually different from those considered by EPA, format item 6 usually will require a separate analysis of environmental introductions due to the proposed use.

(3) Proposed § 25.31(e)(8)(i) has been deleted and replaced by specific

guidance for completing EA format item 15(b).

(4) Format items 7 and 8 advise applicants and petitioners seeking FDA's approval of the FDA-regulated uses to use information in studies submitted to EPA or found in the scientific literature to satisfy FDA's information requirements on environmental fate and effects of the proposed new use.

#### *EA Format 2—Withdrawals of Approval*

91. This format, which is codified in § 25.31b, would generally be used by FDA, rather than by applicants and petitioners, for EA's for nonexcluded actions that would withdraw approval to market or otherwise restrict the uses of FDA-regulated products.

Environmental consideration of actions to withdraw products from the marketplace includes review of the essentiality of the product for which approval would be withdrawn, the availability of substitute products or procedures, and the increased use of these substitutes. Format 2 was developed based on FDA's experience in preparing EIS's and EA's for withdrawals and similar actions.

Format 2 omits certain items that appear in Format 1 that the agency will include in its finding of no significant impact (FONSI) or EIS: the preparer's (i.e., the agency's) name and address, the date, and the certification of the EA's factual accuracy. Items 5, 6, 7, 8, and 9 of Format 1 are all considered under item 2 of Format 2.

#### *EA Format 3—Extramural Grants, Contracts, and Other Agreements*

92. This format, which is codified in § 25.31c, would be used by those submitting proposals to FDA to perform nonexcluded research under a grant by, or contracted other agreement with, FDA. Any subsequent use of research results by FDA, such as to support the approval or withdrawal of approval of an FDA-regulated product, is generally subject to NEPA consideration under other provisions of these regulations. Accordingly, those who conduct FDA-funded research need not include in an EA the potential long-range environmental implications of the various possible findings of proposed research projects. Any attempt to predict such implications at the time research is proposed would be speculative.

#### *EA Format 4—Establishment of Tolerances or Action Levels*

93. Format 4, codified at § 25.31d, would be used in nonexcluded actions



to establish tolerances or action levels for unavoidable or deleterious substances in food for human consumption and food packaging. This format would normally be used by FDA rather than by persons submitting applications or petitions requesting agency actions. Examples of such actions which may have environmental implications include the setting of action levels or tolerances for chemical pollutants such as PCB's in fish or in packaging material. The establishment of tolerances or action levels for pollutants may determine whether certain fish can economically be harvested for human food (and, consequently, whether other types of uncontaminated fish will be harvested more intensively). Tolerances and action levels for food packaging may affect whether certain types of waste papers may be recycled for food-packaging uses. Therefore, the environmental impacts associated with setting tolerances and action levels usually center on changes in the use of natural resources, e.g., fisheries, timberland, agriculture, and in the energy required to obtain or make products within the permissible levels. The establishment of new tolerances or action levels, or the lowering of existing tolerances or action levels, for poisonous or deleterious substances that are unavoidable in food or in food-packaging materials may lead to the use of alternate foods or packaging materials. The impacts resulting from these changes should be discussed to the extent that they can be predicted, e.g., impacts on use of energy and natural resources, removal from the marketplace of the substances that caused the contamination and introduction of chemicals resulting from use of alternate food and packaging.

The establishment of higher tolerances or action levels may preserve or increase the market for the contaminated product and decrease the use of alternate foods and packaging materials. The impact of these changes should be addressed as discussed above.

#### *EA Format 5—Destruction of Condemned, Enjoined, Detained, or Recalled Articles*

94. This format, which is codified at § 25.31e, would be used when FDA determines under § 25.22(c) that the contemplated method of destruction for an FDA-regulated article that has been condemned, detained, or recalled by FDA, or the distribution or use of which has been enjoined, may result in the release of toxic substances into the environment. An EA must be prepared in such cases, upon FDA's request, by

the person who claimed or is otherwise responsible for the article, if no § 25.24 categorical exclusion would apply. The environmental impacts associated with the proposed method of destruction, alternative methods, and mitigation measures are the primary focus of these EA's. In format item 6, alternative methods of destruction (including no action) are considered. Each alternative method of destruction or other methods of disposition, e.g., recycling, should be covered with roughly the same level of detail as was devoted to the proposed method in items 3, 4, and 5.

#### **IV. Subpart D—Agency Decisionmaking**

95. Subpart D corresponds to previous §§ 25.25 and 25.30. The subpart states the procedures FDA uses to incorporate environmental considerations into agency decisionmaking. The purpose of these procedures is to ensure that environmental information is provided to decisionmakers in a timely manner and that the NEPA process is integrated into agency decisionmaking, as required by the CEQ's regulations (40 CFR 1500.5, 1501.4(e), 1502.9(c), 1502.14, 1505.1, 1505.2, 1505.3, 1506.5, 1506.6, and 1506.11).

96. A comment on proposed § 25.41(b)(1) suggested that this provision be modified to state that the EA will not be publicly available until final approval of a pending NDA, ANDA, NADA, or biological product license. Section 25.41(b)(1) concerns the public availability of an EA and FONSI on a proposed action that is the subject of a notice of proposed rulemaking or a notice of filing published in the *Federal Register*. Such a notice shall state that no EIS is necessary and that the EA and FONSI are available for public inspection.

The agency plans to continue, with EA's and FONSI's, its current practice with EIAR's of making these documents available at the time of the public notice of proposed rulemaking for actions requiring a proposal or at the time of notices of filing of food and color additive petitions, EA's and FONSI's for approvals not subject to notices of proposed rulemaking or notices of filing, such as approvals of NDA's, ANDA's, and NADA's, will be made available at the time of the drug's approval.

Additionally, FDA has combined proposed § 25.41(b)(2) and (3) in the final rule at § 25.41(b)(2).

97. A comment on proposed § 25.42(b)(5)(iii) urged that FDA set specific time limits for extensions of time requirements for the agency's preparation of an EIS. The comment expressed concern about long delays in

FDA's review and decisions on applications.

The agency believes that it is not possible to set a specific time limitation applicable to the issuance of all EIS's. Each action requiring the preparation of an EIS and consideration of potentially significant environmental impacts in agency decisionmaking requires different levels of technical input and presents varying levels of complexity and numbers of regulatory alternatives. Time requirements will be extended, if at all, only as long as necessary to permit the agency to issue an EIS for an action. Further, the applicant or petitioner may request a time limit for the preparation of a specific EIS under 40 CFR 1501.8 of CEQ's regulations. The agency will set such time limits for all or part of the NEPA process, consistent with the factors listed in § 1501.8, provided the limits are consistent with the purposes of NEPA.

#### **V. Subpart E—Other Requirements**

98. Subpart E concerns other requirements applicable to environmental effects of the agency's policies.

99. A comment on proposed § 25.50 suggested various changes to clarify the distinction between FDA's evaluation of effects on the environment in the United States (under NEPA) and its evaluation of effects on the environment abroad (under Executive Order 12114). The comment suggested several clarifying changes. Section 25.50 describes the procedures for FDA's consideration of environmental effects abroad of major agency actions in accordance with Executive Order 12114 (44 FR 1957; January 9, 1979). There was no comparable section in FDA's previous regulations in Part 25.

FDA agrees with all of the comment's suggested clarifications and has adopted them in § 25.50 of the final rule.

#### **VI. Economic Impact**

FDA has assessed the economic effects of these regulations and has determined that they are not a major rule as defined in Executive Order 12291. FDA procedures governing environmental impact considerations have been in effect in one form or another since the agency's implementation of NEPA in 1973. This final rule presents definitions of terms and detailed guidance, particularly on determining the need for environmental impact consideration and preparation of environmental assessments and environmental impact statements (when required), which should eliminate or severely reduce unnecessary



environmental impact submissions. Additionally, numerous agency actions are now categorically excluded and several other actions are relieved of the requirement to produce full environmental assessments. These current revisions further streamline the agency's NEPA process through the additional reduction of delays and paperwork, and, therefore, on balance, do not result in any adverse effect on the economy. The regulatory requirements for a regulatory flexibility analysis in the Regulatory Flexibility Act are inapplicable to this rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt from these requirements.

#### Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the collection of information requirements of §§ 25.23(c), 25.31a, 25.31c, and 25.31e in these regulations will be submitted for approval to the Office of Management and Budget (OMB). These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the *Federal Register* prior to July 25, 1985.

#### List of Subjects

##### 21 CFR Part 10

Administrative practice and procedure.

##### 21 CFR Part 25

Environmental impact statements.

##### 21 CFR Part 71

Administrative practice and procedure. Color additive certification. Color additive petitions. Color additives. Cosmetics. Drugs.

##### 21 CFR Part 170

Administrative practice and procedure. Definitions. Food additives. Food additive safety.

##### 21 CFR Part 171

Administrative practice and procedure. Food additive petitions. Food additives.

##### 21 CFR Part 312

Drugs. Medical research.

##### 21 CFR Part 314

Administrative practice and procedure. Drugs.

##### 21 CFR Part 511

Animal drugs. Medical research.

##### 21 CFR Part 514

Administrative practice and procedure. Animal drugs.

##### 21 CFR Part 570

Animal feeds. Animal foods. Food additives.

##### 21 CFR Part 571

Administrative practice and procedure. Animal feeds. Animal foods. Food additives.

##### 21 CFR Part 601

Biologics.

##### 21 CFR Part 812

Health records. Investigational device exemptions. Medical devices. Medical device research. Reporting requirements.

##### 21 CFR Part 813

Intraocular lenses. Medical devices. Medical research.

##### 21 CFR Part 861

Administrative practice and procedure. Medical devices. Performance standards procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371)); under the Public Health Service Act (secs. 351, 354-361, 58 Stat. 702 as amended (42 U.S.C. 262, 263b-264)); under the National Environmental Policy Act of 1969 (sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332)); 40 CFR Parts 1500-1508; Executive Order 11514 as amended by Executive Order 11991; Executive Order 12114; and under 21 CFR 5.11. Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

#### PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. Part 10 is amended in § 10.30(b) by revising item C to read as follows:

##### § 10.30 Citizen petition.

\* \* \*

(b) \* \* \*

##### C. Environmental Impact

(A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.)

\* \* \*

2. By revising Part 25 to read as follows:

#### PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

##### Subpart A—General Provisions

Sec.

25.1 Purpose.

25.5 Policies.

25.10 NEPA planning.

25.15 Terminology.

##### Subpart B—Agency Actions Requiring Environmental Consideration

25.20 General procedures.

25.21 Actions requiring preparation of an environmental impact statement.

25.22 Actions requiring preparation of an environmental assessment.

25.23 Actions that are excluded from the requirement to prepare an environmental assessment.

25.24 Categorical exclusions.

25.25 Retroactive environmental consideration.

##### Subpart C—Preparation of Environmental Documents

25.30 Content and format.

25.31 Environmental assessment formats.

25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1.

25.31b Environmental assessment for withdrawals of approval and other restrictions—Format 2.

25.31c Environmental assessment format for extramural contracts, grants, or other research agreements—Format 3.

25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.

25.31e Environmental assessment for destruction of condemned, enjoined, detailed, or recalled articles—Format 5.

25.32 Finding of no significant impact.

25.33 Notice of intent.

25.34 Draft, final, and supplemental environmental impact statements.

##### Subpart D—Agency Decisionmaking

25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.

25.42 Actions for which an environmental impact statement is prepared.

##### Subpart E—Other Requirements

25.50 Environmental effects abroad of major agency actions.

Authority: Sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371); secs. 351, 354-361, 58 Stat. 702 as amended (42 U.S.C. 262, 263b-264); sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332); 40 CFR Parts 1500-1508; Executive Order 11514 as amended by Executive Order 11991; Executive Order 12114, unless otherwise noted.

##### Subpart A—General Provisions

##### § 25.1 Purpose.

(a) The Food and Drug Administration (FDA) recognizes the National



Environmental Policy Act of 1969 (NEPA) as the national charter for protection, restoration, and enhancement of the environment. NEPA establishes policy, sets goals (section 101), and provides procedures (section 102) for carrying out the policy. This part supplements the regulations for implementing the procedural provisions of NEPA which were published by the Council on Environmental Quality (CEQ) in 40 CFR Parts 1500-1508 and the procedures included in the HHS General Administration Manual, Part 30: Environmental Protection (45 FR 76519-76534, November 19, 1980).

(b) These supplemental procedures provide that: (1) environmental information is to be available to the public and the decisionmaker before decisions are made about actions that may significantly affect the quality of the human environment; (2) FDA actions are to be supported by accurate scientific analyses; and (3) environmental documents are to concentrate on timely and significant issues, not to amass needless detail.

(c) These supplemental procedures for implementing NEPA allow FDA to assist individuals and non-Federal public entities in choosing courses of action that protect and enhance environmental quality.

(d) To avoid delays in decisionmaking, these supplemental procedures make possible the early identification of actions that may significantly affect the quality of the human environment.

(e) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

#### § 25.5 Policies.

(a) All FDA policies and programs will be planned, developed, and implemented so as to achieve the policies declared by NEPA and required by the CEQ regulations to ensure responsible stewardship of the environment for present and future generations.

(b) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under "AUTHORITY" in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, Part 30: Environmental Protection.

(c) Part 30 of the HHS General Administration Manual addresses the following statutes, Executive Orders,

and other authorities not referred to under "AUTHORITY" in this part:

(1) *The Coastal Zone Management Act*, 16 U.S.C. 1456 et seq., directs Federal agencies to conduct activities consistent with an approved State coastal zone management program.

(2) *The Wild and Scenic Rivers Act*, 16 U.S.C. 1278, directs Federal agencies to consider and preserve the values of wild and scenic areas in the use and development of water and land resources.

(3) *Executive Order 11990*, May 24, 1977, directs heads of Federal agencies to avoid the long- and short-term adverse impacts associated with the destruction or modification of wetlands and direct or indirect support of new construction in wetlands whenever there is a practical alternative.

(4) *Executive Order 11988*, May 24, 1977, directs Federal agencies to take action to avoid the occupancy or modification of floodplains and to avoid direct or indirect support of development in floodplain areas whenever there is a practical alternative.

(5) *U.S. Water Resources Council Floodplain Management Guidelines*, February 10, 1978, provides guidance to Federal agencies for implementing Executive Order 11988.

(6) *Marine Protection, Research and Sanctuaries Act*, 33 U.S.C. 1432f, provides for establishment of marine sanctuaries and directs Federal agencies to ensure that their actions are consistent with the intended use of such areas.

(7) *The Safe Drinking Water Act*, 42 U.S.C. 300f, et seq., authorizes EPA to determine if an action which will have an environmental effect on a sole or principal drinking water source would also constitute a significant hazard to a human population and, if so, to prohibit such an action.

(8) *The Clean Air Act*, 42 U.S.C. 1875h-7, requires EPA to review and comment on a Federal agency action which would create a significant environmental impact.

(9) *Executive Order 11987*, May 24, 1977, directs Federal agencies to prevent the introduction of exotic species into the natural ecosystems of the United States.

(10) *The Endangered Species Act*, 16 U.S.C. 1536, directs Federal agencies to conserve endangered and threatened species and their critical habitats.

(11) *Fish and Wildlife Coordination Act*, 16 U.S.C. 661-666c, directs Federal agencies to prevent loss and damage to, and provide for, development and improvement of wildlife resources.

(12) *The National Historic Preservation Act of 1966*, 16 U.S.C. 470 as amended, directs heads of Federal agencies to preserve cultural heritage, particularly with respect to sites on or eligible for listing on the National Register of Historic Places.

(13) *Executive Order 11593*, May 5, 1971, implements portions of the National Historical Preservation Act of 1966 and requires the Federal government to nominate eligible properties which it owns, leases, or otherwise controls.

(14) *Regulations of the Advisory Council on Historic Preservation* (36 CFR Part 800) establish procedures for the protection of historic and cultural properties.

(15) *Regulations of the Department of the Interior* (36 CFR Parts 60 and 63) concern nominations to and determinations of eligibility for the National Register of Historic Places.

(16) *The Archaeological and Historic Preservation Act*, 16 U.S.C. 469a-1, et seq., directs Federal agencies to preserve significant scientific, prehistorical, historical, and archaeological data.

#### § 25.10 NEPA planning.

(a) Environmental impact consideration is an integral part of FDA's regulatory process. For actions initiated by the agency, the process begins when FDA identifies a problem that requires action by the agency under the statutes it administers. For actions initiated by applicants or petitioners, the process begins when FDA receives from an applicant or petitioner an environmental assessment (EA) or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA also may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potentially significant environmental impacts. Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time. FDA's assessment of environmental factors includes the identification of the parts of the environment that may be affected by the action, the evaluation of pertinent environmental data, and the consideration of alternatives consistent with 40 CFR 1502.14.

(b) FDA will be the lead agency for actions under programs it administers. As lead agency, FDA will coordinate the participation of all concerned agencies



in developing an environmental impact statement (EIS) according to 40 CFR 1501.6(a). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

(c) FDA and other affected Federal agencies will agree which one will be the lead agency and which will be the cooperating agencies for actions under programs not administered by FDA. If an agreement cannot be reached, the procedures in 40 CFR 1501.5(e) will be followed.

(d) FDA will act as a cooperating agency if requested. FDA may request to be designated as a cooperating agency if proposed actions may affect areas of FDA responsibility. As a cooperating agency, FDA will comply with the procedures in 40 CFR 1501.6(b) to the extent possible depending on priority and the availability of funds and personnel.

#### § 25.15 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR Part 1508. The terms and the sections of 40 CFR Part 1508 in which they are defined follow:

- (1) Categorical Exclusion (40 CFR 1508.4).
- (2) Cooperating Agency (40 CFR 1508.5).
- (3) Cumulative Impact (40 CFR 1508.7).
- (4) Effects (40 CFR 1508.8).
- (5) Environmental Assessment (EA) (40 CFR 1508.9).
- (6) Environmental Document (40 CFR 1508.10).
- (7) Environmental Impact Statement (EIS) (40 CFR 1508.11).
- (8) Federal Agency (40 CFR 1508.12).
- (9) Finding of No Significant Impact (FONSI) (40 CFR 1508.13).
- (10) Human Environment (40 CFR 1508.14).
- (11) Lead Agency (40 CFR 1508.16).
- (12) Legislation (40 CFR 1508.17).
- (13) Major Federal Action (40 CFR 1508.18).
- (14) Mitigation (40 CFR 1508.20).
- (15) NEPA Process (40 CFR 1508.21).
- (16) Notice of Intent (40 CFR 1508.22).
- (17) Proposal (40 CFR 1508.23).
- (18) Scope (40 CFR 1508.25).
- (19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

- (1) "Agency" means the Food and Drug Administration (FDA).

(2) "Emissions requirements" specifies the limits on the quantities of pollutants allowed to be released into the work place and the area outside a production site or facility. These requirements or standards are set and enforced by local, State, and Federal government components, e.g., Environmental Protection Agency, Occupational Safety and Health Administration.

(3) "Environmental assessment technical guide" means that technical guidance prepared by FDA and intended to assist applicants and petitioners in preparing their environmental assessments.

(4) "Production" includes manufacture, processing, and packaging operations for FDA-regulated articles that are the subject of proposed actions.

(5) "Responsible agency official" means the agency decisionmaker designated in Part 5 of this chapter, the Commissioner of Food and Drugs, or the Commissioner's designated representative.

(6) "Toxic substance" means any substance that is harmful to some biological mechanism or system. Although it is recognized that any substance may produce damage to biological mechanisms or systems under specific conditions, for the purpose of these regulations, a substance is considered to be a toxic substance if it is harmful to appropriate test organisms at expected environmental concentrations even though it may be without effect to humans or other organisms at these concentrations and may even be used by humans because of its toxic properties. A substance is considered toxic in the environment if the maximum concentration of the substance at any point in the environment, i.e., either at any point of entry or any point where higher concentrations are expected as a result of bioaccumulation or other types of concentration processes, exceeds the concentration of the substance that causes any adverse effect in a test organism species (minimum effect level) or exceeds 1/100 of the concentration that causes 50-percent mortality in a test organism species, whichever concentration is less.

(c) The following acronyms are used in this part:

- (1) ANDA—Abbreviated New Drug Application.
- (2) CAS—Chemical Abstracts Service.
- (3) CEQ—Council on Environmental Quality.
- (4) CFR—Code of Federal Regulations.
- (5) CGMP—Current Good Manufacturing Practice.
- (6) EA—Environmental Assessment.

(7) EIS—Environmental Impact Statement.

(8) EPA—Environmental Protection Agency.

(9) FDA—Food and Drug Administration.

(10) FFD&C Act—Federal Food, Drug, and Cosmetic Act.

(11) FIFRA—Federal Insecticide, Fungicide and Rodenticide Act.

(12) FONSI—Finding of No Significant Impact.

(13) GLP—Good Laboratory Practice.

(14) GRAS—Generally Recognized as Safe.

(15) HHS—Department of Health and Human Services.

(16) IDE—Investigational Device Exemption.

(17) INAD—Notice of Claimed Investigational Exemption for New Animal Drug.

(18) IND—Notice of Claimed Investigational Exemption for New Drug.

(19) NADA—New Animal Drug Application.

(20) NDA—New Drug Application.

(21) NEPA—National Environmental Policy Act of 1969.

(22) OTC—Over-the-Counter.

(23) PMA—Premarket Approval Application.

(24) PDP—Product Development Protocol.

(25) TSCA—Toxic Substances Control Act.

(26) U.S.C.—United States Code.

#### Subpart B—Agency Actions Requiring Environmental Consideration

##### § 25.20 General procedures.

(a) These procedures apply to all FDA actions that are not covered by environmental documents prepared under FDA environmental regulations previously in effect.

(b) All agency actions are subject to environmental consideration. Actions are individually examined for potential environmental impact unless excluded as a class by categorical exclusion under § 25.24.

##### § 25.21 Actions requiring preparation of an environmental impact statement.

(a) There are no categories of agency actions which routinely significantly affect the quality of the human environment and which therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when:

- (1) Evaluation of data in an EA leads to a finding by the responsible agency official that a proposed action may



significantly affect the quality of the human environment under the criteria in 40 CFR 1508.14 and 1508.27.

(2) Initial evaluation by the responsible agency official of any action, including any action for which an EA would otherwise be required, establishes that significant environmental effects may be associated with one or more of the probable courses of action being considered.

#### § 25.22 Actions requiring preparation of an environmental assessment.

(a) Any proposed action of a type specified in this paragraph ordinarily requires the preparation of an EA, unless it qualifies for exclusion under §§ 25.23 and 25.24:

(1) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(2) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined.

(3) Destruction or other disposition of articles following detention or recall at agency request.

(4) Disposition of FDA laboratory waste materials.

(5) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants.

(6) Establishment by regulation of labeling requirements, a standard, or a monograph.

(7) Amendments to, or an exemption or variance from, requirements of existing FDA regulations.

(8) Approval of supplements to existing approvals of FDA-approved articles.

(9) Withdrawal of existing approvals of FDA-approved articles.

(10) Approval of food additive petitions and color additive petitions and approval of requests for exemptions for investigational use of food additives.

(11) Establishment of a tolerance or an action level for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(12) Affirmation of a food substance as generally recognized as safe (GRAS) for humans or animals, on FDA's initiative or in response to a petition, under Part 182, 184, 186, or 582.

(13) Promulgation and enforcement of FDA regulations relating to the control of communicable disease and to interstate conveyance sanitation.

(14) Approval of new drug applications (NDA's) and abbreviated new drug applications and actions on

notices of claimed investigational exemption for new drugs (IND's).

(15) Approval of antibiotic application.

(16) Approval and issuance of licenses for biological products.

(17) Approval of new animal drug applications (NADA's), supplements and amendments to NADA's, and notices of claimed investigational exemptions for new animal drugs (INAD's).

(18) Approval of premarket approval applications (PMA's) for medical devices, notices of completion of product development protocols (PDP's) for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an investigational device exemption (IDE).

(19) Action other than one listed in this subsection, unless subject to exclusion under §§ 25.23 and 25.24, that may significantly affect the quality of the human environment.

(b) A person who submits an application or petition requesting action by the agency of a type specified in paragraph (a) of this section shall include an EA for the requested action in the applicable format in § 25.31, unless the action qualifies for exclusion under §§ 25.23 and 25.24. Failure to submit an adequate EA, if one is required, for such an action is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses each of the items specified in the applicable format in § 25.31. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(c) A manufacturer, distributor, or dealer who proposes to destroy or otherwise dispose of an FDA-regulated article that has been condemned, detained, or recalled, or whose distribution or use has been enjoined shall, if requested by the agency, submit an EA in the applicable format prescribed in § 25.31 analyzing the environmental impact of the proposed disposition of such article or shall provide information establishing that the action qualifies for exclusion under §§ 25.23 and 25.24.

(d) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. FDA is responsible for ensuring the accuracy of the EA, as required by 40 CFR 1506.5(b). If significant effects requiring the preparation of EIS are

identified, FDA will publish in the **Federal Register** a Notice of Intent to prepare an EIS in accordance with § 25.33 of this part. If significant effects requiring the preparation of an EIS are not anticipated and the decision is made not to prepare an EIS, the responsible agency official will prepare a finding of no significant impact (FONSI) in accordance with § 25.32.

#### § 25.23 Actions that are excluded from the requirement to prepare an environmental assessment.

(a) Actions of a class that individually or cumulatively have been determined under § 25.24 not to significantly affect the quality of the human environment ordinarily are excluded from the preparation of an EA or an EIS.

(b) As required under 40 CFR 1508.4, FDA will require an EA for any specific action that ordinarily is excluded if the agency has sufficient evidence to establish that the specific proposed action may significantly affect the quality of the human environment.

(c) A person submitting an application or petition of a type subject to categorical exclusion under § 25.24, or proposing to dispose of an article as provided in § 25.24 (a)(4) or (b)(9), is not required to submit an EA if the person specifies the provision of this part that excludes the action from the requirement for an EA and provides information, when appropriate, that establishes to the agency's satisfaction that the action requested is included within an excluded category and meets the criteria for the applicable exclusion.

(d) Failure to provide sufficient information, when appropriate, to establish that the requested action is subject to a categorical exclusion under § 25.24 may result in the agency's refusal to file or to approve the application or petition or to approve the proposed disposition of an article as provided in § 25.24 (a)(4) or (b)(9).

#### § 25.24 Categorical exclusions.

Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because, as a class, these actions will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment. (These actions are listed in paragraphs (a) (1) through (3), (5), (7) through (9), (b) (1), (4) through (6), and 8(ii), (c) (3), (5), (8), (9), and (11), (d) (2), (3), and (5), (e) (1) through (3) and (5) of this section.) Additional exclusions for actions that will not result in the



introduction of any substance into the environment are contained in Chapter 30-20-40 B.2. of the HHS General Administration Manual. Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because these actions meet specific criteria that are intended to ensure that they will not cause significant environmental effects. (These actions are listed in paragraphs (a) (4), (6), (10), and (11), (b) (2), (3), (7), (8)(i), and (9), (c) (1), (2), (4), (6), (7), and (10), (d) (1), (4), (6), and (7), (e) (4), (6), and (7) of this section.) Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because, as a class, these actions are routine maintenance or minor leasing or construction activities conducted or contracted for by FDA. (These actions are listed in paragraph (a)(12) of this section.) The classes of actions that are categorically excluded are as follows:

(a) *General.* (1) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(2) Recommendation for an enforcement action to be initiated in a Federal court.

(3) Agency requests for initiation of recalls.

(4) Destruction or disposition of any article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment.

(5) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(6) Extramural contracts, other agreements, and grants for research for such purposes as to develop analytical methods or other test methodologies if the waste from such research will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(7) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(8) Issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval.

(9) Corrections and technical changes in regulations.

(10) Promulgation of current good manufacturing practice (CGMP) regulations, establishment standards, emergency permit control regulations, and good laboratory practice (GLP) regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations; if there is no increase in the quantities or toxicity of wastes entering the environment as a direct or indirect result of the action.

(11) Establishment or repeal by regulation of labeling requirements for marketing articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(12) Routine maintenance and minor construction activities, except for properties listed on or eligible for listing on the National Register of Historic Places:

(i) Repair to or replacement of equipment or structural components (doors, roof, window, etc.) of facilities controlled by FDA;

(ii) Lease extensions, renewals, or succeeding leases;

(iii) Construction or lease construction of 10,000 square feet or less of occupiable space;

(iv) Relocation of employees into existing owned or currently leased space;

(v) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(vi) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(b) *Foods, food additives, and color additives.* (1) Promulgation, amendment, or repeal of a food standard.

(2) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies for research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(3) Approval of a color additive petition to change a provisionally listed

color additive to permanent listing for use in food, drugs, devices, or cosmetics if data available to the agency do not establish that, at the expected levels of exposure, it may be toxic to organisms in the environment.

(4) Testing and certification of batches of a color additive.

(5) Promulgation of an interim food additive regulation.

(6) Establishment of an action level under section 402(a) of the Federal Food, Drug, and Cosmetic Act for natural or unavoidable defects in food for humans or animals if these defects present no health hazard.

(7) Affirmation of a food substance as generally recognized as safe (GRAS) for humans or animals on FDA's initiative or in response to a petition, under Part 182, 184, 186, or 582, if the substance is already marketed for the use for which affirmation is sought and data available to the agency do not establish that, at the expected levels of exposure, the substance may be toxic to organisms in the environment.

(8) Promulgation and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under:

(i) Part 1240 if the method of control (including treatments, destruction, or disposition) of any animal or article, including packaging material, does not affect an endangered species or result in the release of a toxic substance into the environment; or

(ii) Part 1250 if the corrective measures do not result in the release of a toxic substance into the environment.

(9) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feed if such disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment.

(c) *Human drugs and biological products.* (1) Action on an ANDA if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment.

(2) Action on an amendment or supplement to an NDA of the following types if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected levels of exposure, the



substance may be toxic to organisms in the environment.

(i) Changes specified in § 314.70 (c) or (d); or

(ii) Any other type of amendment or supplement to an NDA which meets the above criteria for exclusion.

(3) Withdrawal of approval of an NDA or ANDA when the drug is no longer being marketed or at the request of the application holder.

(4) Action on a Notice of Claimed Investigational Exemption for New Drug (IND), if the drug shipped under such notice is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(5) Testing and certification of batches of an antibiotic or insulin.

(6) Promulgation, revocation, or amendment of a monograph for a drug that is not a new drug, for an antibiotic drug, or for an over-the-counter (OTC) drug, if the drug is already marketed for the proposed use and data available to the agency do not establish that, at the expected levels of exposure, the drug may be toxic to organisms in the environment.

(7) Establishment of bioequivalence requirements for a marketed drug product if there is no change in the existing levels of use or intended uses of the product.

(8) Action on changes in a biological product license or an establishment license reported under § 601.12 of this chapter.

(9) Revocation of a license for a biological product when it is no longer being marketed, or revocation of a biological product or establishment license at the request of the license holder.

(10) Promulgation, amendment, or revocation of a standard for a licensed biological product or amendment of the license for a biological product if there is no change in the existing levels of use or intended uses of the product.

(11) Action on a license application for transfusable blood or blood products.

(d) *Animal drugs.* (1) Action on an NADA or supplemental NADA for a previously approved animal drug of the following types if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment:

(i) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(ii) A combination of previously approved animal drugs;

(iii) A new premix or other formulation of a previously approved animal drug;

(iv) Changes specified in § 514.8(a) (5), (6), or (d);

(v) A change of sponsor; or

(vi) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 or as a liquid feed supplement under § 558.5.

(2) Approval of an animal feed bearing or containing a drug approved under § 514.2 or 514.9.

(3) Withdrawal of approval of an NADA when the drug is no longer being marketed or at the request of the application holder.

(4) Action on a notice of claimed investigational exemption for a new animal drug (INAD) if the drug to be shipped under such notices is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(5) Testing and certification of batches of an antibiotic for animal use.

(6) Promulgation, revocation, or amendment of a monograph for an animal drug that is not a new animal drug, if the drug is already being marketed for the proposed use and data available to the agency do not establish that, at the expected levels of exposure, the drug may be toxic to organisms in the environment.

(7) Establishment of bioequivalence requirements for marketed animal drug products if there is no change in the existing levels of use or intended uses of the product.

(e) *Devices and electronic products.*

(1) Action on a device premarket notification submission under Subpart E of Part 807.

(2) Classification or reclassification of a device under Part 860.

(3) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(4) Approval of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device and data available to the agency do not establish that approval of the PMA, or the notice of completion of the PDP or amended or

supplemental applications or notices, will result in release of substances that, at the expected levels of exposure, may be toxic to organisms in the environment.

(5) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(6) Promulgation of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(7) Action on an application for an Investigational Device Exemption (IDE) or an authorization to commence a clinical investigation under an approved Product Development Protocol (PDP), if the devices shipped under such notices are intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(8) Promulgation of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

#### § 25.25 Retroactive environmental consideration.

(a) FDA may consider the need for preparing an EIS for an existing FDA regulation, approval, or other action, whether or not previously subject to environmental analysis, when there is new information before the agency that suggests that the action may significantly affect the quality of the human environment.

(b) If FDA notifies an applicant or petitioner who obtained an existing FDA approval that new information suggests that the approval may have significant environmental effects and that an EA is therefore required, the applicant or petitioner shall submit an EA as described in § 25.31 for the approval. A notification under this paragraph will be in writing.

#### Subpart C—Preparation of Environmental Documents

##### § 25.30 Content and format.

(a) Sections 25.31 through 25.34 describe the environmental documents that may be required in the course of the agency's consideration of the environmental aspects of an action. These sections delineate the relationships of these documents to each other and their purpose, contents, and format. Additional information



concerning the nature and scope of information that an applicant or petitioner shall submit in an environmental document may be obtained on a case-by-case basis from the bureau, national center, or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA environmental assessment technical guides, which describe protocols for environmental studies and discuss the interpretation results.

(b) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in environmental documents prepared under this part. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner may submit such data and information separately as a confidential section of the application or petition, but shall summarize the confidential data and information in the environmental document to the extent possible.

#### § 25.31 Environmental assessment formats.

(a) As defined by CEQ in 40 CFR 1508.9, the EA is the public document in which environmental and other pertinent information on a proposed action are presented, providing a basis for the agency's determination whether to prepare as EIS or a FONSI.

(b) An EA shall be prepared in the format presented in this section for each action not categorically excluded in § 25.24. The EA shall be a complete, objective, and well-balanced document that allows the public to understand the agency's decision.

(c) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

#### § 25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1.

(a) For proposed actions to approve food or color additives, drugs, biological products, animal drugs, and class III medical devices, and to affirm food substances as generally recognized as safe (GRAS), the applicant or petitioner shall prepare an environmental assessment in the following format:

##### Environmental Assessment

1. Date:
2. Name of applicant/petitioner:

##### 3. Address:

##### 4. Description of the proposed action:

Briefly describe the requested approval; need for the action; the locations where the products will be produced; to the extent possible, the locations where the products will be used and disposed of; and the types of environments present at and adjacent to those locations.

##### 5. Identification of chemical substances

that are the subject of the proposed action: Provide complete nomenclature, CAS Reg. No. (if available), molecular weight, structural formulae, physical description, additives, and impurities. This information is required to be adequate to allow accurate location of data about chemicals in the scientific literature and to allow identification of closely related chemicals.

6. Introduction of substances into the environment: For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed action will have upon compliance with current emissions requirements at the production site(s). Through use of calculations and/or direct measures, estimate to the extent possible the quantities and concentrations of substances expected to enter the environment as a result of use and/or disposal of products affected by the action.

7. Fate of emitted substances in the environment: Predict environmental concentrations of and exposures to substances entering the environment as a consequence (direct or indirect) of the use and/or disposal of the products affected by the action for the following environmental compartments, including consideration of the major environmental transport and transformation processes involved:

(a) Air—taking into account, to the extent possible, factors such as volatilization, photochemical and chemical degradation, rainout, and dispersion;

(b) Freshwater, estuarine, and marine ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, exchange between the water column and sediments via sorption/desorption and biological processes, accumulation in animals, plants, and other organisms, introductions due to rainfall and losses due to volatilization;

(c) Terrestrial ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, sorption/desorption and leaching in soils, accumulation in animals and plants, introductions due to rainfall, losses due to volatilization, and entry into groundwater.

8. Environmental effects of released substances: Given the information developed on the introduction (item 6) and fate (item 7) of substances which would be released as a consequence of the use and/or disposal of the products affected by the action, use any relevant toxicological data or other appropriate measures to predict, to the extent applicable, effects on animals, plants, humans, other organisms, and effects at the

ecosystem-level in each of the environmental compartments listed in item 7.

9. Use of resources and energy: Specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of a given amount of any product which is the subject of the action, including the resources and energy required to dispose of wastes generated from production, use, and/or disposal. Effects, if any, upon endangered or threatened species and upon property listed in or eligible for listing in the National Register of Historic Places must be discussed.

10. Mitigation measures: Describe measures taken to avoid or mitigate potential adverse environmental impacts associated with the proposed action.

11. Alternatives to the proposed action: If potential adverse environmental impacts have been identified for the proposed action, describe in detail the environmental impact of all reasonable alternatives to the proposed action (including no action, and including measures that FDA or another government agency could undertake as well as those the applicant/petitioner would undertake). Describe particularly those alternatives that will enhance the quality of the environment and avoid some or all of the adverse environmental impacts of the proposed action. Discuss the environmental benefits and risks of the proposed action. Discuss the environmental benefits and risks of each alternative.

12. List of preparers: Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

13. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date) \_\_\_\_\_

(Signature of responsible official)

(Title) \_\_\_\_\_

14. References: List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

15. Appendices: (a) Data summary charts (e.g., structural formula, vapor pressure, water solubility, *n*-octanol/water partition coefficient, biodegradation half-life, *LC*<sub>50</sub> for each species tested, etc.).

(b) Test reports (for each experiment: research objective, experimental design and procedure, all data relevant to interpretation of the test result given in item 15(a), sample calculations and statistical analyses).

(b) FDA has determined that, for the following actions, certain requirements of the environmental assessment format in paragraph (a) of this section may be abbreviated as specified in this paragraph. All other format items in paragraph (a) of this section are required to be addressed in full. After FDA evaluates environmental



information submitted in an EA in which one or more format items are abbreviated, FDA may require the submission of additional information on the subject in question.

(1) For actions to approve food additive petitions for food additives present in finished food-packaging material at not greater than 5-percent-by-weight, the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production of the food additive, list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). For food additives that are present as functional components of finished food-packaging material, estimate the maximum yearly market volume of the additive for the proposed use and the percent of that amount that will be a component of the finished food-packaging material. This information may be used to determine whether the proposed additive has potential for significant environmental introductions at the sites of production and disposal of the food-packaging material. For food additives that are used in the production of and that become nonfunctional components of finished food-packaging material, estimate the maximum yearly market volume of the additive for the proposed use, the percent of that amount that will be a component of the finished food-packaging material, and the concentrations of the proposed food additive expected to enter the environment at the site of production of the food-packaging material. This information may be used to determine whether the proposed additive has potential for significant environmental introductions at the sites of production and disposal of the food-packaging material.

(ii) *Format item 7.* For food additives that become nonfunctional components of finished food-packaging material, report or incorporate by reference physical/chemical and other data relating to the environmental fate of the additive developed for other purposes in the petition and where pertinent data in the scientific literature are known. Examples of such physical/chemical parameters include water solubility, *n*-octanol/water partition coefficient, vapor pressure, etc. These data may be used to make a rough estimate of environmental concentration and

mobility of the food additive at the site of production of the food-packaging material. Documentation of environmental fate is normally not required for food additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight.

(iii) *Format item 8.* For food additives that become nonfunctional components of food-packaging material, report or incorporate by reference existing data relating to the environmental effects of the proposed food additive. Toxicity of the proposed food additive to laboratory animals (submitted to satisfy human safety requirements) and information on the toxicity of the product to organisms that may be exposed in the environment, e.g., fish, invertebrates, plants, fungi, and bacteria, known from the scientific literature should be reported. The expected environmental concentrations of the proposed food additive should be compared with the concentrations that caused adverse toxicological effects. Documentation of environmental effects is normally not required for additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight.

(iv) *Format item 9.* Documentation for this item is ordinarily not required if the proposed food additive is intended for the same use as another additive already in use and will not materially change the potential uses of the packaging material to which it is added.

(v) *Format items 10 and 11.* For food additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight, documentation for these items is normally not required. For food additives that become nonfunctional components of finished food-packaging material at not greater than 5-percent-by-weight, these format items are addressed in full.

(2) For approval of food additives to be used as components of food-contact surfaces of permanent or semi-permanent equipment or of other food-contact articles intended for repeated use, the following information is required for the items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed food additive will have upon compliance with current emissions requirements at the

production site(s). To determine whether approval of the proposed food additive will result in potentially significant introductions of substances into the environment due to the disposal of food-contact articles containing the proposed food additives, estimate the maximum yearly market volume of the proposed food additive.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(3) For approval of NDA's for human drugs and approval of licenses for biological products, when the drugs or biological products are intended for the prevention, treatment, or diagnosis of a rare disease or for a similarly infrequent use; for ophthalmic or topical application; or for local or general anesthesia; the following information is required for the items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). Estimate the maximum yearly market volume of the drug product to aid in determining whether approval of the application could result in potentially significant environmental introductions from use of the product.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(4) For approval of NADA's and supplements and amendments to NADA's for animal drugs intended for use under prescription or veterinarian's order; for treatment of a disease occurring in minor species animals, as defined in § 514.1(d); for use in nonfood animals; for ophthalmic or topical application; or for local or general anesthesia; the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). Estimate the maximum yearly market volume of the drug product to aid in determining whether approval of the application will result in potentially



significant environmental introductions from use of the product.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(5) When the agency approves or issues, for a substance that occurs naturally in the environment, a food or color additive petition, GRAS affirmation petition, NDA, supplemental NDA, biological product license, NADA, supplemental NADA, or class III medical device, the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; and include a citation of, and statement of compliance with, applicable emissions requirements at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s).

(ii) *Format item 7.* Discuss whether the use of the product can reasonably be expected on the basis of all available evidence to alter significantly the concentration and distribution of the product, its metabolites, degradation products, or its constituent parts in the environment.

(iii) *Format item 8.* Report existing data relating to the environmental effects of substances expected to be emitted into the environment as a consequence of use of the product. Report information obtained from the scientific literature on the toxicity of the product to laboratory animals, e.g., that information which is submitted to satisfy human safety requirements, and to organisms in the environment, e.g., fish, invertebrates, plants, fungi, and bacteria, that may be exposed to the product.

(6) For approval or issuance by the agency of a food or color additive petition, NDA, supplemental NDA, biological product license, NADA, or supplemental NADA for a product that has been approved by the Environmental Protection Agency (EPA) under section 4 or 5 of the Toxic Substances Control Act (TSCA) or under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the following information is required:

(i) *Format items 7 and 8.* To address these items, rely on environmental information in studies submitted to EPA, in the application/petition submitted for FDA approval, and in the scientific literature. Describe any potential adverse environmental impacts determined by EPA.

(ii) *Format item 15(b).* For studies submitted to EPA or for relevant studies

submitted in the application/petition to meet the requirements of the Federal Food, Drug, and Cosmetic Act, test reports may include only a brief description and summary of results of each study in lieu of attaching complete test reports.

#### § 25.31b Environmental assessment for withdrawals of approval and other restrictions—Format 2.

For proposed actions to withdraw approval or otherwise restrict or reduce the use of food or color additives, drugs, biological products, animal drugs, and class III medical devices, any environmental assessment prepared by the agency will be in the following format:

##### Environmental Assessment

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the uses and the magnitude (production volume and/or sales) of such uses for the product(s) for which approval would be withdrawn or otherwise restricted or reduced and for the available substitute products. Determine those uses of the restricted product(s) for which no substitute products are available and the magnitude and essentiality of such uses. Discuss the environmental impacts of (1) reducing or eliminating environmental exposures to the restricted product; (2) natural resources and energy used in producing, distributing, using, and disposing of the restricted product compared with those required for the available substitute products; (3) any expected increased production and use of substitute products; and (4) essential uses of the restricted product for which there would be no substitutes.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced

articles not generally available should be attached.

8. *Appendices:* Append detailed physical, chemical, biological, and environmental data on products that are the subject of the proposed action.

#### § 25.31c Environmental assessment format for extramural contracts, grants, or other research agreement—Format 3.

For extramural contracts, grants, or other research agreements subject to environmental assessment, the contractor or applicant shall use the following format:

##### Environmental Assessment

1. *Date:*
2. *Name of prospective contractor/applicant:*
3. *Address:*
4. *Description of the proposed research activities:* Briefly describe the purpose of the proposed research, the locations where the research activities would occur, and the types of environments present at those locations.
5. *Information on the chemical substances and infectious agents to be used:* Provide the information listed in Table 1 on each of the chemical substances and infectious agents to be used in the research activity, to the extent that they can be identified, either specifically or generically, and including such items as organic solvents as well as the chemicals of major research interest.

TABLE 1.—CHEMICAL SUBSTANCES/INFECTIOUS AGENTS TO BE USED IN THE PROPOSED RESEARCH ACTIVITIES

Chemical infectious agent name (complete scientific nomenclature)	Approximate amounts to be used *	Hazard code *	Emissions controls: (environmental and occupational) *
1.			
2.			
3.			

\* Specify in metric units of mass or volume.  
\* I—infectious, C—carcinogenic, M—mutagenic, T—teratogenic, A—acutely toxic or poison, COR—corrosive, E—explosive or flammable, R—radioactive, O—other hazard, please specify, NH—nonhazardous.  
\* Examples include use of fume hoods, use of protective clothing/gear by laboratory personnel, chemical inactivation of wastes, separation of hazardous from nonhazardous wastes, and subsequent disposal by a firm licensed for this purpose.

6. *Compliance with Federal, State, and local environmental and occupational requirements.* Cite and include a statement of compliance with applicable emissions requirements (including occupational) at the Federal, State, and local level. Discuss the effect that the proposed research will have upon compliance with these requirements.

7. *List of preparers:* Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

8. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the prospective contractor or applicant submitting the environmental assessment.



(Date) \_\_\_\_\_  
 (Signature of responsible official) \_\_\_\_\_  
 (Title) \_\_\_\_\_

**§ 25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.**

For proposed actions to establish tolerances or action levels for unavoidable poisonous or deleterious substances in food for human or animal consumption or in packaging materials intended for use with human food and animal feed, the agency will prepare an environmental assessment in the following format:

**Environmental Assessment**

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the potential environmental impacts of the proposed action including effects on natural resources and energy, effects on food production, effects on land use, and impacts resulting from increased use and changes in use patterns for chemical substances.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

**§ 25.31e Environmental assessment for destruction of condemned, enjoined, detained, or recalled articles—Format 5.**

For actions to destroy or dispose of articles condemned after seizure, detention, or FDA-initiated recall, or after distribution or use of the article has been enjoined, the person proposing the action shall, at the request of the agency, prepare an environmental

assessment in the following format when the method of destruction or disposition results in release of toxic substances:

**Environmental Assessment**

1. *Purpose of and need for action:* Briefly describe the underlying purpose and need for the article to be destroyed, the proposed method of destruction or disposal, the locations where the proposed destruction or other disposal will occur, and the types of environments present at and adjacent to those locations.

2. *Description of potentially toxic substances present in the article:* Provide complete nomenclature, CAS Registry numbers (if available), molecular weight, structural formulae, physical description, and concentration of the potentially toxic substances in the article.

3. *Introduction of potentially toxic substances into the environment:* For transport of the article to the site(s) of disposition, cite and certify compliance with any applicable Federal, State, and local emissions requirements. List to the extent possible the potentially toxic substances expected to enter the environment at the site(s) of destruction and/or disposal of the article. Describe the approximate concentrations of emissions; state the controls exercised; and include a citation of, and statement of compliance with, applicable requirements at the Federal, State, and local level.

4. *Fate of potentially toxic emitted substances in the environment:* Report physical/chemical and other data in the scientific literature relating to the fate of potentially toxic substances expected to be emitted into the environment as a result of destruction or other disposal of the article. Such physical/chemical parameters include water solubility, solubility in organic solvents, *n*-octanol/water partition coefficient, dissociation constants, vapor pressure, ultraviolet-visible absorption spectrum, ability to form chemical complexes, storage stability, etc.

5. *Environmental effects of potentially toxic substances expected to be emitted into the environment:* Report information on the effects of the emitted substances on animals, plants, humans, other organisms, and effects at the ecosystem level. Compare the expected environmental concentrations of the substances with the concentrations that cause adverse effects.

6. *Description of alternative methods of destruction and/or disposal and the expected environmental consequences:* Describe the environmental impact of reasonable alternatives (including no action) particularly those that will enhance the quality of the environment and that will avoid some or all of the adverse environmental effects of the proposed method of destruction or other disposition.

7. *Comparative analysis of proposed methods of destruction or other disposition and alternative methods:* Provide a comparative analysis of the environmental benefits and risks of the proposed and alternative methods. Identify the preferred action based on environmental factors.

8. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

9. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

**§ 25.32 Finding of no significant impact.**

(a) As defined by the CEQ regulations (40 CFR 1508.13), a finding of no significant impact (FONSI) is a document prepared by a Federal agency and stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) If the EA has been prepared by an applicant or petitioner, the agency may choose to include additional evidence in the FONSI. Any remaining unknowns or uncertainties will be identified.

(c) The agency official(s) responsible for the preparation and approval of the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusions not to prepare an EIS for the action under consideration.

**§ 25.33 Notice of intent.**

(a) As defined by CEQ regulations (40 CFR 1508.22), the Notice of Intent notifies the public that the agency has determined that an EIS will be prepared. This determination may be based on information contained in an EA or on other information available to the agency which indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the Notice of Intent will describe the proposed action, possible alternatives, the agency's proposed scoping process, which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings, and the identification of persons within the agency to contact for further information.

**§ 25.34 Draft, final, and supplemental environmental impact statements.**

(a) The CEQ regulations (40 CFR Part 1502) provide detailed requirements for the preparation of an EIS. CEQ's format for EIS's (40 CFR 1502.10) will be followed unless the agency determines that there is a compelling reason to do otherwise.

(b) When chemical substances enter the environment as a result of a proposed action or other regulatory



alternatives, the portion of the EIS format on "environmental consequences" (40 CFR 1502.10(g)) will include discussion of the environmental fates and effects of those substances similar to that described in § 25.31a.

(c) Any final EIS will contain any additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments as required in 40 CFR 1503, including any revisions resulting from comments or other information.

(d) Draft and final supplemental EIS's will conform to the EIS format (40 CFR 1502.10) unless there is a compelling reason to do otherwise.

#### Subpart D—Agency Decisionmaking

##### § 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The NEPA process is an integral part of FDA's decisionmaking. Agency decisionmakers ensure that the policies and purpose of NEPA and GEQ regulations are complied with by:

(1) Completing or assuring the completion of an EA, determining whether an EIS is required and, ordinarily, completing a draft EIS (if one is required) prior to or at the time of proposing an action subject to §§ 25.21 and 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision as required by 40 CFR 1502.14. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.

(4) Including in the records of proceedings any appropriate environmental documents, comments, and responses.

(5) Completing and circulating a final EIS before the decision to implement an action that significantly affects the quality of the human environment.

(b) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of the CEQ regulations and these regulations concerning minimum

periods of public review impractical. Compliance with the requirements for environmental analysis under NEPA is impossible where emergency circumstances require immediate regulatory action to safeguard the public health. For such actions, the responsible agency official shall consult with the CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

(c) Certain FDA actions are subject to statutory time limits that sometimes do not provide sufficient time to complete the required environmental document. Should the responsible agency official be unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the *Federal Register* document publishing the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in the FDA Dockets Management Branch. If it is concluded that an EIS is necessary, the final regulation, final EIS, and record of decision shall be made available as prescribed in 40 CFR 1506.10.

##### § 25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.

(a) As required by 40 CFR 1501.4(e), a FONSI is prepared for an individual action or groups of related actions that will not significantly affect the quality of the human environment. If potentially adverse environmental impacts are identified for an action or group of related actions, the EA supporting the FONSI will, as required by 40 CFR 1508.9, include a consideration of any reasonable alternative courses of action that offer less environmental risk or that are environmentally preferable to the proposed action.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the *Federal Register*, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at the FDA Dockets Management Branch.

(2) For actions for which notice is not published in the *Federal Register*, the FONSI and the EA shall be made available to the public upon request

according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA available for public review (including review by State and areawide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

(c) Program area officials and environmental staff prepare or ensure that the information contained in an EA is complete and accurate, and they prepare the FONSI. The responsible agency official designated in Part 5 examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

##### § 25.42 Actions for which an environmental impact statement is prepared.

(a) An individual action or group of related actions requires the preparation of an EIS when significant environmental impacts may be associated with one or more of the probable courses of action. The responsible agency official weights any environmental impacts of each alternative course of action, including possible mitigation measures, and selects the course of action that is consistent with the applicable law and the agency's environmental analysis of the action.

(b) For actions for which an EIS is prepared, the public has the opportunity to offer comments and otherwise participate in the NEPA process as set forth in 40 CFR 1506.6 from the time the decision is made to prepare the document as described in this paragraph:

(1) A Notice of Intent to prepare an EIS is prepared for publication in the *Federal Register* and serves as the first public notification that an EIS will be prepared.

(2) The scoping process, as announced in the Notice of Intent, allows the public and Federal, State, and local government agencies to participate in determining the issues to be considered in the EIS.

(3)(i) Draft EIS's are filed with the EPA, sent to parties having an interest



in the document, and are available to the public upon request for the purpose of receiving substantive comment, corrections, and additional information on the issues covered.

(ii) If the subject of a draft EIS is also the subject of a notice of proposed rulemaking, the **Federal Register** notice of proposed rulemaking will state that the draft EIS is available upon request, and will solicit comments from all interested persons.

(iii) If the subject of a draft EIS is not also the subject of a notice of proposed rulemaking published in the **Federal Register**, FDA will publish a notice in the **Federal Register** describing the proposed action and possible alternatives, stating that the draft EIS is available upon request, and soliciting comments from all interested persons.

(iv) FDA will solicit comments from any Federal agency having jurisdiction by law or having expertise on the environmental impact of a proposed action by sending it a copy of a draft EIS.

(v) Two copies of all comments on draft EIS's shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857 (except individuals may submit one copy) where they will be available for public inspection from 9 a.m. to 4 p.m., Monday through Friday.

(vi) Draft EIS's will be prepared, forwarded to EPA for filing, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. Except in emergencies, no final action will be taken on the proposal earlier than 90 days after a draft EIS has been prepared, forwarded to the EPA, and made available to the public.

(4) The final text of an EIS will be prepared by the responsible agency official after comments on the draft statement have been reviewed and will receive full consideration in the agency's decisionmaking process. The responsible agency official will forward 10 copies of the final statement to the Office of the Secretary of the Department of Health and Human Services and 10 copies to the EPA, and FDA will make copies of the final statement available for public inspection in the Dockets Management Branch. Copies of each final EIS will be available upon request and will be forwarded to those persons who submitted comments on the pertinent draft statements.

(5)(i) The weighing of any environmental impacts of alternatives in

selecting a final course of action, as described in paragraph (a) of this section, will be reflected in the agency record of formal decisionmaking as required by 40 CFR 1505.2.

(ii) Except in emergencies, no agency action will be effective earlier than 30 days after the final statement has been filed for public inspection by EPA. If the subject of a final statement is also the subject of a regulation published in the **Federal Register**, this requirement may be met by simultaneous publication of the regulation and of a notice of availability of the final statement and the record of decision, provided that the regulation becomes effective no sooner than 30 days after the date of publication.

(iii) If the subject of an EIS is an FDA action governed by specific time requirements under statute or regulations, those time requirements will be extended, if at all, only as long as necessary to permit the agency to consider or issue an EIS for the action.

(c) As described in 40 CFR 1505.3, the agency may provide for monitoring to ensure that its decisions, any mitigating measures, and other conditions are carried out.

(d) Under the conditions prescribed in 40 CFR 1502.9(c), the agency will prepare a supplement for a draft or final EIS and introduce the supplement into its administrative record.

(e)(1) The agency official to whom authority for the action is delegated in Part 5 will ensure both that there is balancing of environmental impacts with the agency's objective in choosing an appropriate course of action and that the public is involved and notified of the decision, as described in paragraphs (a) through (d) of this section.

(2)(i) The director of each FDA center is responsible for preparing a draft or final EIS on actions delegated to that center by the Commissioner under Subpart B of Part 5 of this chapter or in which the center is a party in an administrative proceeding under Part 12, 13, 14, 15, or 16 of this chapter in which a draft or final EIS is required.

(ii) The Director, Office of Regional Operations, FDA, is responsible for preparing a draft or final EIS on the destruction of articles condemned after seizure, subject to an injunction, under import detention, or under detention or recalled at agency request.

(iii) The Office of the Commissioner of Food and Drugs is responsible for preparing or assigning the task of preparing a draft or final EIS on actions not otherwise assigned in this section.

## Subpart E—Other Requirements

### § 25.50 Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions" of January 4, 1979 (44 FR 1957; January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine in accordance with section 2-3 of the Executive Order whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine in accordance with section 2-4(a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2-5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

## PART 71—COLOR ADDITIVE PETITIONS

3. Part 71 is amended by revising item j in § 71.1(c), to read as follows:



**§ 171.1 Petitions.**

(c) \* \* \*

J. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**PART 170—FOOD ADDITIVES**

4. Part 170 is amended by adding new paragraph (c)(1)(viii) to § 170.35, to read as follows:

**§ 170.35 Affirmation of generally recognized as safe (GRAS) status.**

(c) \* \* \*

(1) \* \* \*

(viii) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**PART 171—FOOD ADDITIVE PETITIONS**

5. Part 171 is amended:

a. By revising item H in § 171.1(c), to read as follows:

**§ 171.1 Petitions.**

(c) \* \* \*

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**§ 171.6 [Amended]**

b. In § 171.6 *Amendment of petition* by removing the third sentence.

**PART 312—NEW DRUGS FOR INVESTIGATIONAL USE**

6. Part 312 is amended by revising item 15 in § 312.1(a)(2), to read as follows:

**§ 312.1 Conditions for exemption of new drugs for investigational use.**

(a) \* \* \*

(2) \* \* \*

15. A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**PART 314—NEW DRUG APPLICATIONS**

7. Part 314 is amended:

a. By revising § 314.50(d)(1)(iii), to read as follows:

**§ 314.50 Content and format of an application.**

(d) \* \* \*

(1) \* \* \*

(iii) *Environmental impact.* The application is required to contain either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

b. By revising § 314.101(d)(4), to read as follows:

**§ 314.101 Filing an application.**

(d) \* \* \*

(4) The applicant fails to submit a complete environmental assessment which addresses each of the items specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

**PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE**

8-9. Part 511 is amended by revising § 511.1(b)(10), to read as follows:

**§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the Act.**

(b) \* \* \*

(10) The sponsor shall submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**PART 514—NEW ANIMAL DRUG APPLICATIONS**

10. Part 514 is amended:

a. By revising § 514.1(b)(14), to read as follows:

**§ 514.1 Applications.**

(b) \* \* \*

(14) *Environmental assessment.* The applicant is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

b. By revising the last sentence of § 514.8(a)(1), to read as follows:

**§ 514.8 Supplemental new animal drug applications.**

(a) (1) \* \* \* A supplemental application shall be accompanied by either a claim for categorical exclusion under § 25.24 of this chapter or an

environmental assessment under § 25.31 of this chapter.

**§ 514.9 [Amended]**

c. In § 514.9 *Supplemental applications for animal feeds bearing or containing new animal drugs* by removing paragraph (d).

d. By adding § 514.110(b)(10), to read as follows:

**§ 514.110 Reasons for refusing to file applications.**

(b) \* \* \*

(10) The applicant fails to submit a complete environmental assessment which addresses each of the items specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

e. By revising § 514.111(a)(9), to read as follows:

**§ 514.111 Refusal to approve an application.**

(a) \* \* \*

(9) The applicant fails to submit an adequate environmental assessment under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

**PART 570—FOOD ADDITIVES**

11. Part 570 is amended by adding § 570.35(c)(1)(viii), to read as follows:

**§ 570.35 Affirmation of generally recognized as safe (GRAS) status.**

(c) \* \* \*

(1) \* \* \*

(viii) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

**PART 571—FOOD ADDITIVE PETITIONS**

12. Part 571 is amended:

a. By revising item H in § 571.1(c), to read as follows:

**§ 571.1 Petitions.**

(c) \* \* \*

H. The petitioner is required to submit either a claim for categorical exclusion under



§ 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.  
\* \* \*

**§ 571.6 [Amended]**

b. In § 571.6 *Amendment of petition* by removing the third sentence.

**PART 601—LICENSES**

13. Part 601 is amended by revising the next-to-last sentence in § 601.2(a), to read as follows:

**§ 601.2 Applications for establishment and product licenses; procedures for filing.**

(a) \* \* \* The applicant shall also include either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter. \* \* \*

**PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

14. Part 812 is amended by revising § 812.20(b)(9), to read as follows:

**§ 812.20 Application.**

\* \* \*  
(b) \* \* \*

(9) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.  
\* \* \*

**PART 813—INVESTIGATIONAL EXEMPTIONS FOR INTRAOCULAR LENSES**

15. Part 813 is amended by revising § 813.20(b)(17), to read as follows:

**§ 813.20 Application.**

\* \* \*  
(b) \* \* \*

(17) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.  
\* \* \*

**PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT**

**§ 861.26 [Amended]**

16. Part 861 is amended in § 861.26 *Offer to develop a proposed standard* by removing paragraph (a)(4) and marking it "reserved."

*Effective date.* This regulation shall become effective July 25, 1985.

(Sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371); secs. 351, 354-361, 58 Stat. 702 as amended (42 U.S.C. 262, 263b-264); sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332)).

**Frank E. Young,**

*Commissioner of Food and Drugs.*

Dated: January 14, 1985.

**Margaret M. Heckler,**

*Secretary of Health and Human Services.*

[FR Doc. 85-10087 Filed 4-25-85; 8:45 am]

BILLING CODE 4160-01-M



PART I—SYMPTOMS AND SIGNS	PART II—DIAGNOSIS AND TREATMENT	PART III—PROGNOSIS AND PREVENTION
1. Fever 2. Headache 3. Stiff neck 4. Photophobia 5. Nausea and vomiting	1. History 2. Physical examination 3. Laboratory tests 4. Differential diagnosis	1. Course of disease 2. Complications 3. Prognosis 4. Prevention
6. Rash 7. Meningeal signs 8. Cerebral signs 9. Spinal fluid examination	5. Pathology 6. Bacteriology 7. Virology 8. Immunology	5. Vaccines 6. Serums 7. Antitoxins 8. Prophylaxis
10. Pathology 11. Bacteriology 12. Virology 13. Immunology	9. Pathology 10. Bacteriology 11. Virology 12. Immunology	9. Pathology 10. Bacteriology 11. Virology 12. Immunology
14. Pathology 15. Bacteriology 16. Virology 17. Immunology	13. Pathology 14. Bacteriology 15. Virology 16. Immunology	13. Pathology 14. Bacteriology 15. Virology 16. Immunology
18. Pathology 19. Bacteriology 20. Virology 21. Immunology	17. Pathology 18. Bacteriology 19. Virology 20. Immunology	17. Pathology 18. Bacteriology 19. Virology 20. Immunology
22. Pathology 23. Bacteriology 24. Virology 25. Immunology	21. Pathology 22. Bacteriology 23. Virology 24. Immunology	21. Pathology 22. Bacteriology 23. Virology 24. Immunology
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34. Pathology 35. Bacteriology 36. Virology 37. Immunology	33. Pathology 34. Bacteriology 35. Virology 36. Immunology	33. Pathology 34. Bacteriology 35. Virology 36. Immunology
38. Pathology 39. Bacteriology 40. Virology 41. Immunology	37. Pathology 38. Bacteriology 39. Virology 40. Immunology	37. Pathology 38. Bacteriology 39. Virology 40. Immunology
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70. Pathology 71. Bacteriology 72. Virology 73. Immunology	69. Pathology 70. Bacteriology 71. Virology 72. Immunology	69. Pathology 70. Bacteriology 71. Virology 72. Immunology



# Federal Register

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Friday  
April 26, 1985

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## Part V

### Department of Education

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34 CFR Parts 350, 352, 358, and 359  
National Institute of Handicapped  
Research; Final Regulations



**DEPARTMENT OF EDUCATION****34 CFR Parts 350, 352, 358, and 359****National Institute of Handicapped Research****AGENCY:** Department of Education.**ACTION:** Final regulations.

**SUMMARY:** The Secretary issues final regulations governing some programs of the National Institute of Handicapped Research. These regulations implement certain changes to Titles II and III of the Rehabilitation Act of 1973 made by Pub. L. 98-221, the Rehabilitation Amendments of 1984.

These regulations establish criteria for the evaluation of applications for financial assistance under a new program of Innovation Grants and for a program of Special Projects in Spinal Cord Injury. They also establish conditions under which the Secretary may elect not to terminate funding to a Research and Training Center at the conclusion of its funding period.

**EFFECTIVE DATE:** These regulations will take effect either 45 days after publication in the *Federal Register* or later if Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

**FOR FURTHER INFORMATION CONTACT:** Betty Jo Berland, National Institute of Handicapped Research, Department of Education, 400 Maryland Avenue SW., Room 3070, Switzer Building, Washington, D.C. 20202. 732-1139; deaf or hearing impaired individuals may call (202) 732-1198 for TTY services.

**SUPPLEMENTARY INFORMATION:** The National Institute of Handicapped Research (NIHR), created under Title II of the Rehabilitation Act of 1973, as amended by Pub. L. 95-602, carries out a variety of research and related activities under that statutory authority. On September 10, 1981, the Secretary published final program regulations governing many of those activities (46 FR 45300), and on March 12, 1984 and June 18, revised those regulations (49 FR 9324, 24978). These further amendments to the regulations implement changes to the Act affecting NIHR made by Pub. L. 98-221, the Rehabilitation Amendments of 1984, enacted on February 22, 1984. On November 23, 1984, the Secretary published in the *Federal Register* a Notice of Proposed Rulemaking (49 FR 46244) covering technical amendments to several programs of the National Institute of Handicapped Research.

The amendments to the Act authorize a new program of innovation grants under section 204(b)(13) to test new concepts and innovative ideas; demonstrate research results of high potential benefits; purchase prototype aids and devices for evaluation; develop unique rehabilitation training curricula; and respond to special initiatives of the Secretary. These amendments to the regulations implement this new program authority and include rules to establish eligibility requirements, provide criteria for evaluation of applications, and provide a method for selection of successful applicants.

The Act, as amended, further provides that regulations and administrative procedures with respect to financial assistance under the Innovation Grants program be expedited to the maximum extent possible. These regulations simplify the selection criteria for reviewing applications under this program, and permit periodic peer review and award of funds within a fiscal year to ensure more timely funding of innovative projects under the program.

The Act was also amended to provide that Research and Training Centers (RTCs) need not necessarily be terminated at the conclusion of the project period. These regulations establish criteria and procedures to enable the Secretary to decide whether to continue without competition a specific RTC grant at the conclusion of the funding period.

In adopting this provision, the Congress provided for those exceptional circumstances in which it would be a major disadvantage to discontinue funding a particular RTC. It is the Secretary's understanding that this provision is meant to be invoked only in unusual circumstances, and that competition remains the principal means of obtaining financial assistance under this program.

In addition, the legislation transfers authority for the administration of the special projects and demonstrations program for spinal cord injuries from the Rehabilitation Services Administration (RSA) to NIHR. These amendments to the regulations include provisions, with selection criteria, to implement that program in NIHR.

The Secretary requested public comment on the proposed regulations. A number of comments were received and fully considered in preparation of these final regulations. A summary of comments and responses follows these regulations.

**Part 350—Handicapped Research: General Provisions**

The Secretary amends §§ 350.1, 350.3, 350.20, 350.30, 350.34, and 350.40 so that appropriate provisions of Part 350, generally applicable to NIHR programs, apply to the new Innovation Grants program and to the Special Projects and Demonstrations for Spinal Cord Injuries program, for which the administrative functions were recently transferred to NIHR.

**Part 352—Handicapped Research: Rehabilitation Research and Training Centers**

The Secretary amends § 352.10(c) to authorize grantees to use grant funds for faculty support and to require grantees who do so to give priority to the training of students preparing to be rehabilitation personnel. These provisions implement amendments to section 204(b)(1) of the Act made by section 123(a) of Pub. L. 98-221.

A new § 352.33 permits the Secretary to renew a Rehabilitation Research and Training Center grant without competition at the end of the project period on the basis of specified criteria. This section implements a provision added to section 204(b)(1) of the Act by section 123(a) of Pub. L. 98-221.

**Part 358—Handicapped Research: Innovation Grants Program***Subpart A—General*

Sections 358.1-358.4 describe the purpose of the Innovation Grants program and incorporate provisions of Part 350 relating to eligibility, applicable regulations, and definitions. The Secretary has decided that 34 CFR 75.217(c)-(e) of the Education Department General Administrative Regulations (EDGAR) will not apply to the Innovation Grants Program. Those provisions describe how the Secretary normally selects applications for new grants under the Department's discretionary programs and provide for the creation of a rank ordering of applications based solely on the evaluations of those applications by groups of experts. The Secretary believes that a rank ordering is unnecessary and would be unworkable as applied to the Innovation Grants Program, since applications will be reviewed, and awards made, throughout the fiscal year as provided in proposed § 358.31. While the Secretary exempts this program from the rank ordering requirements of 34 CFR 75.217(c)-(e), the remaining provisions of those regulations have been incorporated into § 358.31.



**Subpart B—What Kinds of Activities Does the Secretary Support Under This Program?**

Section 358.10 describes specific types of projects and activities that may be supported under the Innovation Grants program.

**Subpart D—How Does the Secretary Make a Grant?**

Section 358.30 incorporates the peer review procedures of §§ 350.30–350.32.

Sections 358.31–358.33 describe how the Secretary invites applications, the selection criteria used by the peer review panel and the Secretary, and additional factors the Secretary considers in selecting grantees.

**Part 359—Handicapped Research: Special Projects and Demonstrations for Spinal Cord Injuries**

**Subpart A—General**

Sections 359.1–359.4 describe the purpose of the program, identify eligible applicants, and incorporate provisions of Part 350 relating to regulations and definitions.

**Subpart B—What Kinds of Activities Does the Secretary Support Under This Program?**

Section 359.10 describes specific types of projects and activities that may be supported under this program.

Section 359.11 describes certain activities that each grantee must carry out.

**Subpart D—How Does the Secretary Make A Grant?**

Section 359.30 incorporates the peer review procedures of §§ 350.30–350.32.

Section 359.31 describes the selection criteria by which the Secretary and the peer review panel review applications.

**Executive Order 12291**

These regulations have been reviewed in accordance with Executive Order 12291.

They are not classified as major because they do not meet the criteria for major regulations established in the Order.

**Paperwork Reduction Act of 1980**

Information collection requirements contained in these regulations (§ 358.31) have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511).

**Assessment of Educational Impact**

In the Notice of Proposed Rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that

is being gathered by or is available from any other agency or authority of the United States.

Based upon the comments on the proposed rule and the Department's own review, it has been determined that the regulations in this document do not require information that is being gathered by or is available from any other agency or authority of the United States.

**List of Subjects**

**34 CFR Part 350**

Administrative practice and procedure, Education, Educational research, Grant programs—education, Handicapped.

**34 CFR Part 352**

Education, Educational research, Grant programs—education, Handicapped, Manpower training programs, Vocational rehabilitation.

**34 CFR Part 358**

Education, Educational research, Grant programs—education, Handicapped, Reporting and recordkeeping requirements, Vocational rehabilitation.

**34 CFR Part 359**

Education, Educational research, Grant programs—education, Handicapped, Vocational rehabilitation.

**Citation of Legal Authority**

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these final regulations.

(Catalog of Federal Domestic Assistance No. 84.133, National Institute of Handicapped Research)

Dated: April 22, 1985.

William J. Bennett,

Secretary of Education.

The Secretary amends Title 34 of the Code of Federal Regulations by revising Parts 350 and 352 and adding new Parts 358 and 359 as follows:

**PART 350—HANDICAPPED RESEARCH: GENERAL PROVISIONS**

1. In § 350.1, paragraph (b) is revised to read as follows:

**§ 350.1 Handicapped research.**

(b) The Secretary awards financial assistance through nine types of programs:

- (1) Research and demonstration projects (34 CFR Part 351).
- (2) Research grants for establishment and operation of rehabilitation research and training centers (34 CFR Part 352).

(3) Research grants for establishment and operation of rehabilitation engineering centers (34 CFR Part 353).

(4) Research grants for establishment and operation of model training centers (34 CFR Part 354).

(5) Knowledge dissemination and research utilization projects (34 CFR Part 355).

(6) Research fellowships (34 CFR Part 356).

(7) Field-initiated research projects (34 CFR Part 357).

(8) Innovation Grants projects (34 CFR Part 358).

(9) Special Projects and Demonstrations for Spinal Cord Injuries (34 CFR Part 359).

(Secs. 200 and 204; 29 U.S.C. 760 and 762)

2. In § 350.3, paragraphs (a) and (c) are revised to read as follows:

**§ 350.3 What regulations apply to these programs?**

(a) The Education Department General Administrative Regulations (EDGAR), established in title 34 of the Code of Federal Regulations in—

(1) Part 74 (Administration of Grants);

(2) Part 75 (Direct Grant Programs), except as noted in 34 CFR 352.33 and 358.3;

(3) Part 77 (Definitions that Apply to Department Programs); and

(4) Part 78 (Education Appeal Board);

(c) The regulations in 34 CFR Parts 351, 352, 353, 354, 355, 357, 358, or 359, as appropriate; and

3. Section 350.20 is revised to read as follows:

**§ 350.20 What are the application procedures for these programs?**

An applicant for assistance under 34 CFR Parts 351, 352, 353, 354, 355, 357, 358, or 359 shall submit a copy of its application to the State rehabilitation agency for comment in accordance with the procedures in EDGAR, 34 CFR 75.155–75.159.

(Secs. 204(c) and 306(i); 29 U.S.C. 762(c) and 766(a))

4. Section 350.30 is revised to read as follows:

**§ 350.30 To whom does the Secretary refer an application?**

The Secretary refers each application for a grant under the Handicapped Research Programs to a peer review panel established by the Secretary. Peer review panels review applications for the Secretary on the basis of selection criteria described in 34 CFR 350.34, 358.32 or 359.31, as appropriate.



(Sec. 202(e); 29 U.S.C. 761a(e))

5. The heading of § 350.34 is revised to read as follows, and the table of contents of Part 350 is amended accordingly:

**§ 350.34 What selection criteria does the Secretary use in reviewing applications under Parts 351, 352, 353, 354, 355, and 357?**

6. In § 350.40, paragraph (b) is revised to read as follows:

**§ 350.40 What are the matching requirements?**

(b)(1) The Secretary may make grants to pay for part or all of the costs of the following activities:

- (i) Establishment and support of Rehabilitation Research and Training Centers, Rehabilitation Engineering Centers, and Model Training Centers.
- (ii) Research and other special projects and demonstrations concerned with spinal cord injury.
- (iii) Research projects concerned with end-stage renal disease, telecommunications, rehabilitation of handicapped children and handicapped individuals who are aged sixty or older, attracting and retaining rehabilitation professionals in rural areas, producing and distributing captioned video cassettes for deaf individuals, and innovative methods of providing services for handicapped children and their parents.
- (iv) Joint projects with other Federal agencies and private industry.
- (v) Research to test new concepts and innovative ideas.
- (vi) International programs of research, demonstration, training, exchange of experts, and technical assistance.

(2) The Secretary determines at the time of the award whether the grantee must pay a portion of the project or center costs.

(Sec. 204; 29 U.S.C. 762)

## **PART 352—HANDICAPPED RESEARCH: REHABILITATION RESEARCH AND TRAINING CENTERS**

7. In § 352.10, paragraph (c) is revised by adding at the end thereof two sentences to read as follows:

**§ 352.10 What types of centers are authorized under this program?**

(c) \* \* \* Grantees may also use grant funds for faculty support for teaching of rehabilitation related courses of study for credit and other courses offered by

the institutions of higher education affiliated with the Center. Each grantee that uses grant funds for this purpose shall give priority to training of students preparing to be rehabilitation personnel.

8. A new § 352.33 is added to read as follows, and the table of contents of Part 352 is amended accordingly:

**§ 352.33 May the Secretary renew a Research and Training Center grant without competition?**

(a) Notwithstanding the provisions of EDGAR, 34 CFR § 75.253(d), the Secretary may renew a Rehabilitation Research and Training Center (RTC) grant without competition at the end of the project period if—

(1) The RTC is performing work in an area of continued high priority to the Secretary and is working on long-range solutions to rehabilitation problems;

(2) The RTC has submitted to the Secretary, not later than 15 months before the end of its project period, a formal request for renewal without competition;

(3) The RTC has submitted to the Secretary no later than 12 months before the expiration of its current project period a proposal for the activities to be conducted during the period for which funding is being requested;

(4) The Secretary has determined on the basis of documentation or expert consultation, that the Center may be a unique national resource and to discontinue it might be contrary to the interests of the Government, and that further consideration of the request for exemption from competition is warranted through an independent review of the Center and its application for the ensuing grant period;

(5) An independent peer review panel has reviewed the activities and products of the Center, including an on-site review where necessary, has reviewed the proposal for the new project period, and has made a recommendation to the Secretary on whether the Center should be continued; and

(6) The Secretary has determined, on the basis of the above factors, that to discontinue the work of the Center would result in an irretrievable loss of potential advances in knowledge and of substantial prior investment, and would be contrary to the interests of the Government.

(b) A noncompetitive award may be for a period up to 60 months. No Center may be renewed for more than 60 months beyond its original project period without competition.

(Sec. 204(b)(1); 29 U.S.C. 762(b)(1))

9. A new Part 358 is added to read as follows:

## **PART 358—HANDICAPPED RESEARCH: INNOVATION GRANTS PROGRAM**

### **Subpart A—General**

Sec.

358.1 What is the Innovation Grants program?

358.2 Who is eligible for assistance under this program?

358.3 What regulations apply to this program?

358.4 What definitions apply to this program?

358.5–358.9 [Reserved]

### **Subpart B—What Kinds of Activities Does the Secretary Assist Under This Program?**

358.10 What types of projects are authorized under this program?

358.11–358.19 [Reserved]

### **Subpart C—[Reserved]**

### **Subpart D—How Does the Secretary Make a Grant?**

358.30 How is peer review conducted under this program?

358.31 How does the Secretary select applications for new grants?

358.32 What selection criteria does the Secretary use in reviewing applications under this program?

358.33 What are the priorities for funding under this program?

358.34 What is the maximum amount of a grant for any fiscal year?

358.35–358.39 [Reserved]

Authority: Section 204(b)(13) of the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended by Pub. L. 98-221, 98 Stat. 23-24 (29 U.S.C. 762(b)(13)), unless otherwise noted.

### **Subpart A—General**

**§ 358.1 What is the Innovation Grants program?**

This program is designed to provide financial support to projects that—

(a) Test new concepts and innovative ideas;

(b) Demonstrate research results of high potential benefits;

(c) Purchase and evaluate prototype aids and devices;

(d) Develop unique rehabilitation training curricula; and

(e) Respond to special initiatives of the Secretary, including projects to conduct feasibility, planning, and evaluation studies, conferences, and other activities to disseminate specific research findings.

(Sec. 204(b)(13); 29 U.S.C. 762(b)(13))



**§ 358.2 Who is eligible for assistance under this program?**

The agencies and organizations eligible to apply under this program are described in 34 CFR 350.2

(Sec. 204; 29 U.S.C. 762)

**§ 358.3 What regulations apply to this program?**

The regulations referenced in 34 CFR 350.3 apply to this program, except for 34 CFR 75.217(c)-(e).

(Sec. 204; 29 U.S.C. 762)

**§ 358.4 What definitions apply to this program?**

The definitions listed in 34 CFR 350.4 apply to this program.

(Sec. 202(i)(1); 29 U.S.C. 761a(i)(1))

**§§ 358.5-358.9 [Reserved]****Subpart B—What Kinds of Activities Does the Secretary Assist Under This Program?****§ 358.10 What types of projects are authorized under this program?**

The Innovation Grants program provides financial assistance for the following types of projects:

(a) Research, demonstration, and related activities to test new concepts and innovative ideas in rehabilitation of disabled individuals or to demonstrate research results of high potential benefits.

(b) Research, demonstration, and related activities which are responsive to special initiatives of the Secretary, are unique or innovative, or could not be carried out in a timely manner under the Institute's other programs.

(c) Projects to purchase and evaluate prototype aids and devices, or to demonstrate innovative approaches to producing, testing, marketing, and distributing selected aids and devices.

(d) Projects to develop and test unique rehabilitation training curricula, including training for rehabilitation-related research as well as any rehabilitation-related services.

(e) Research, demonstration, or development projects, feasibility studies, planning activities, evaluation studies dissemination of information, conferences, surveys or statistical analyses, or policy studies in areas concerned with improved rehabilitation, especially those which offer timely opportunities for high potential benefit or which must be conducted expeditiously if their potential benefits are to be realized.

(Sec. 204(b)(13); 29 U.S.C. 762(b)(13))

**§§ 358.11-358.19 [Reserved]****Subpart C—[Reserved]****Subpart D—How Does the Secretary Make a Grant?****§ 358.30 How is peer review conducted under this program?**

(a) The Secretary may, at any time, convene a peer review panel to review an application received in response to an application notice.

(b) Peer review is conducted under this program in accordance with 34 CFR 350.30-350.32, using the selection criteria in § 358.32.

(Secs. 202(e) and 204(b)(13); 29 U.S.C. 761a(e) and 762(b)(13))

**§ 358.31 How does the Secretary select applications for new grants?**

(a) After the peer review panel evaluates an application, the Secretary reviews and selects an application on the basis of—

(1) Scientific and technical merit, in accordance with the selection criteria in § 358.32;

(2) The priorities in § 358.33, if appropriate; and

(3) Any other requirement that applies to the selection of applications for new grants.

(b) In selecting an application for a new grant, the Secretary may consider the following:

(1) The information in the application.

(2) The evaluation of the application by the peer review panel.

(3) Any other information relevant to a criterion, priority, or other requirement that applies to the selection of applications for new grants.

(c) (1) The Secretary may, at any time, select an application for funding under this part.

(2) If the Secretary does not select an application for funding when it is reviewed under this section, the Secretary may select it for funding at a later date in the same fiscal year.

(Secs. 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i)(1))

(Approved by the Office of Management and Budget under control number 1820-0027)

**§ 358.32 What selection criteria does the Secretary use in reviewing applications under this program?**

The Secretary uses the criteria in this section to evaluate applications under this program. The maximum score for all the criteria is 100 points.

(a) *Importance of the project* (50 points).

The Secretary reviews each application to determine to what degree the proposed activity will address a

significant need of the target population and will meet the purposes of this part.

(b) *Project design or methodology* (25 points).

The Secretary reviews each application to determine to what degree the underlying hypothesis or conceptual model is sound; the project design is likely to achieve the desired objectives; and the evaluation plan is appropriate.

(c) *Plan of operation* (25 points).

The Secretary reviews each application to determine the extent to which the qualifications and background of the key personnel, the management and financial plan, and the capability and resources of the applicant organization demonstrate that the applicant will be able to carry out the proposed project.

(Sec. 204(b)(13); 29 U.S.C. 762(b)(13))

**§ 358.33 What are the priorities for funding under this program?**

The Secretary may give priority to applications that have been awarded a rating of 60 points or more under § 358.32 and meet one or both of the following conditions:

(a) The proposed project represents a unique opportunity to conduct research, demonstrate, evaluate, disseminate, train, or prepare for advances in knowledge to improve rehabilitation services to disabled persons.

(b) The proposed project is particularly pertinent to rehabilitation needs at that time and is likely to contribute important knowledge in a timely manner.

(Sec. 204(b)(13); 29 U.S.C. 762(b)(13))

**§ 358.34 What is the maximum amount of a grant for any fiscal year?**

The maximum amount of a grant under this program for any fiscal year is \$50,000.

(Sec. 204(b)(13); 29 U.S.C. 762(b)(13))

**§§ 358.35-358.39 [Reserved]**

10. A new Part 359 is added to read as follows:

**PART 359—HANDICAPPED RESEARCH: SPECIAL PROJECTS AND DEMONSTRATIONS FOR SPINAL CORD INJURIES**

**Subpart A—General**

Sec.

359.1 What is the Special Projects and Demonstrations for Spinal Cord Injuries program?

359.2 Who is eligible for assistance under this program?

359.3 What regulations apply to this program?

359.4 What definitions apply to this program?



359.5-359.9 [Reserved]

#### Subpart B—What Kinds of Activities Does the Secretary Assist Under This Program?

359.10 What types of projects are authorized under this program?

359.11 What activities must each recipient carry out under this program?

359.12-359.19 [Reserved]

#### Subpart C—[Reserved]

#### Subpart D—How Does the Secretary Make A Grant?

359.30 How is peer review conducted under this program?

359.31 What selection criteria does the Secretary use in reviewing applications under this program?

359.32-359.39 [Reserved]

Authority: Section 311(a) of the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended by Pub. L. 98-221, 98 Stat. 23-24 (29 U.S.C. 777a(a)), unless otherwise noted.

#### Subpart A—General

##### § 359.1 What is the Special Projects and Demonstrations for Spinal Cord Injuries Program?

This program provides assistance to establish innovative projects for the delivery, demonstration, and evaluation of comprehensive medical, vocational, and other rehabilitation services to meet the wide range of needs of individuals with spinal cord injuries.

(Sec. 311(a); 29 U.S.C. 777a(a))

##### § 359.2 Who is eligible for assistance under this program?

Public and other nonprofit agencies and organizations are eligible to apply for assistance under this program.

(Sec. 311(a); 29 U.S.C. 777a(a))

##### § 359.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Secs. 202(i)(1) and 311(a); 29 U.S.C. 761a(i)(1) and 777a(a))

##### § 359.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Secs. 202(i)(1) and 311(a); 29 U.S.C. 761(i)(1) and 777a(a))

§§ 359.5-359.9 [Reserved]

#### Subpart B—What Kinds of Activities Does the Secretary Assist Under This Program?

##### § 359.10 What types of projects are authorized under this program?

This program provides assistance for demonstration projects that—

(a) Provide comprehensive rehabilitation services to individuals with spinal cord injuries; and

(b) Conduct spinal cord research, including clinical research and the analysis of standardized data in collaboration with other related projects.

(Sec. 311(a) of the Act; 29 U.S.C. 777a(a))

##### § 359.11 What activities must each recipient carry out under this program?

Each recipient, whether administering a project separately under this part or in coordination with other activities supported under Title II of the Act, shall—

(a) Establish a multidisciplinary system of providing rehabilitation services specifically designed to meet the special needs of individuals with spinal cord injuries, including emergency medical services, acute care, vocational and other rehabilitation services, community and job placement, and long-term community follow up and health maintenance. The system must be established on an appropriate geographical basis that reflects patterns of patient flow, and must be administered in close coordination with similar programs of the Veterans Administration, the National Institutes of Health, and other public and private agencies and institutions where appropriate;

(b) Demonstrate and evaluate both the service and cost benefits of a regional service system to those individuals with spinal cord injuries who might be served within that system;

(c) Establish within the system a rehabilitation research environment for the achievement of new knowledge leading to the reduction and treatment of complications arising from spinal cord injury and the development of new techniques of medical management and rehabilitation;

(d) Demonstrate and evaluate the development and application of improved methods and equipment essential to the care, management, and rehabilitation of individuals with spinal cord injury;

(e) Demonstrate methods of community outreach and education for individuals with spinal cord injury in areas such as housing, transportation, recreation, employment, and other community activities; and

(f) Participate as directed by the Secretary in national studies of the benefits of a spinal cord injury service system by contributing to a national database and by other means as required by the Secretary.

(Sec. 311(b); 29 U.S.C. 777a(b))

§§ 359.12-359.19 [Reserved]

#### Subpart C—[Reserved]

#### Subpart D—How Does the Secretary Make a Grant?

##### § 359.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30-350.32, using the selection criteria in § 359.31.

(Sec. 202(e) and 311(a); 29 U.S.C. 761a(e) and 777a(a))

##### § 359.31 What selection criteria does the Secretary use in reviewing applications under this program?

The Secretary uses the criteria in this section to evaluate applications under this program. The maximum score for all the criteria is 100 points.

(a) *Project design* (20 points).

The Secretary reviews each application to determine to what degree—

(1) There is a clear description of how the objectives of the project relate to the purpose of the program;

(2) The research is likely to produce new and useful information;

(3) The need and target population are adequately defined;

(4) The outcomes are likely to benefit the defined target population;

(5) The research hypotheses are sound; and

(6) The research methodology is sound in the sample design and selection, the data collection plan, the measurement instruments, and the data analysis plan.

(b) *Service comprehensiveness* (20 points).

The Secretary reviews each application to determine to what degree—

(1) The services to be provided within the project are comprehensive in scope, and include emergency medical services, intensive and acute medical care, rehabilitation management, psychosocial and community reintegration, and follow up;

(2) A broad range of vocational and other rehabilitation services will be available to severely handicapped individuals within the project; and

(3) Services will be coordinated with those services provided by other appropriate community resources.

(c) *Plan of operation* (15 points).

The Secretary reviews each application to determine to what degree—

(1) There is an effective plan of operation that ensures proper and efficient administration of the project;



(2) The applicant's planned use of its resources and personnel is likely to achieve each objective;

(3) Collaboration between institutions, if proposed, is likely to be effective; and

(4) There is a clear description of how the applicant will include eligible project participants who have been traditionally underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(d) *Quality of key personnel* (10 points).

The Secretary reviews each application to determine to what degree—

(1) The principal investigator and other key staff have adequate training or experience, or both, in spinal cord injury care and rehabilitation and demonstrate appropriate potential to conduct the proposed research, demonstration, training, development, or dissemination activity;

(2) The principal investigator and other key staff are familiar with pertinent literature or methods, or both;

(3) All the disciplines necessary to establish the multidisciplinary system described in § 359.11(a) are effectively represented;

(4) Commitments of staff time are adequate for the project; and

(5) The applicant is likely, as part of its non-discriminatory employment practices, to encourage applications for employment from persons who are members of groups that traditionally have been underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(e) *Adequacy of resources* (10 points).

The Secretary reviews each application to determine to what degree—

(1) The facilities planned for use are adequate;

(2) The equipment and supplies planned for use are adequate; and

(3) The commitment of the applicant to provide administrative and other necessary support is evident.

(f) *Budget/cost effectiveness* (10 points).

The Secretary reviews each application to determine to what degree—

(1) The budget for the project is adequate to support the activities;

(2) The costs are reasonable in relation to the objectives of the project; and

(3) The budget for subcontracts (if required) is detailed and appropriate.

(g) *Dissemination/utilization* (5 points).

The Secretary reviews each application to determine to what degree—

(1) There is a clearly defined plan for dissemination and utilization of project findings;

(2) The research results are likely to become available to others working in the field;

(3) The means to disseminate and promote utilization by others are defined; and

(4) The utilization approach is likely to address the defined need.

(h) *Evaluation plan* (10 points).

The Secretary reviews each application to determine to what degree—

(1) There is a mechanism to evaluate plans, progress and results;

(2) The evaluation methods and objectives are likely to produce data that are quantifiable; and

(3) The evaluation results, where relevant, are likely to be assessed in a service setting.

(Secs. 202(e) and 311(a); 29 U.S.C. 761a(e) and 777a(a))

#### §§ 359.32-359.39 [Reserved]

#### Appendix

This Appendix will not be codified in the Code of Federal Regulations.

#### Summary of Comments and Responses

Comment: Some commenters stated that there should be no provision for exempting Research and Training Centers from competition at the expiration of their project periods and that all activities funded by NIHR should be funded on the basis of competition.

Response: No change has been made. While the Secretary supports the principle of competition for financial assistance, the Secretary is adopting these amendments to the regulations as required to implement the intent of the statute.

Comment: Several commenters objected to the statement in the preamble indicating that competition would be the preferred means of obtaining financial assistance and that exemption from competition was intended to be used only in exceptional circumstances. They urged that NIHR regard funding without competition as a standard means of funding RTCs in areas of ongoing priorities, while competition would be used in new priorities.

Response: No change has been made. Competition is the standard policy of the Department, and the Secretary believes that

competition for financial assistance is generally the best means of assuring high quality of research, affording fairness to the research community, and serving the best interests of disabled people. In providing that RTCs need not be automatically terminated, Congress authorized the Secretary to make exceptions to that policy when circumstances warrant.

Comment: A few commenters stated that the decisions on funding applicants should be made by the Director of NIHR, who is required by law to be knowledgeable about rehabilitation research, rather than by the Secretary.

Response: No change has been made. The Secretary is the chief executive officer of the Department of Education. The Education Department General Administrative Regulations (34 CFR Part 77), define "Secretary" to include an official or employee of the Department of Education acting for the Secretary under a delegation of authority. The Secretary receives advice from other officials of the Department based upon their substantive knowledge and expertise.

Comment: Some commenters suggested that the requirement for on-site reviews in the process of determining whether to exempt RTCs from competition could be burdensome or too costly under some circumstances and that reviews off-site might be sufficient.

Response: A change has been made. The regulations now permit off-site reviews, as well as on-site reviews when necessary.

Comment: A few commenters urged that the evaluation criteria for the Innovation Grants program be made more rigorous and conform to those in the Field-Initiated Research program.

Response: No change has been made. While the Secretary agrees that the quality of funded research should not be diluted, the Secretary is mindful that the law requires that administrative procedures for these grants be expedited as much as possible, and notes that the emphasis of the program is on the support of innovative concepts.

Comment: Several commenters suggested that there should be more attention to the evaluation of research design in the criteria for selection of Spinal Cord Injury applications.

Response: A change has been made. The selection criteria have been modified to provide specific attention to research factors such as soundness of hypotheses, sample selection, data collection, and data analysis.

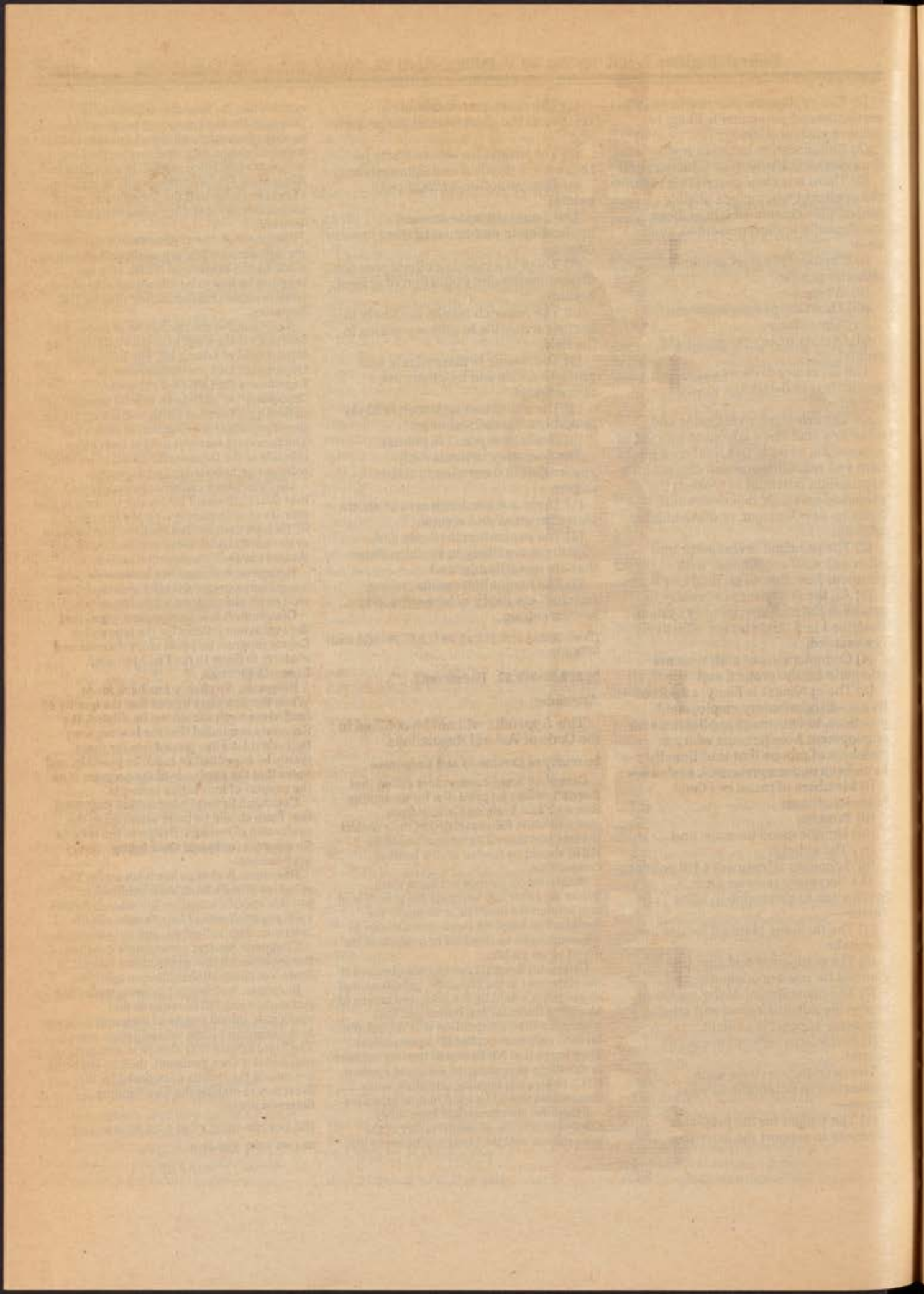
Comment: Several commenters questioned the requirement that applications be sent to State Vocational Rehabilitation agencies.

Response: No change has been made. The Act authorizing NIHR requires that applicants submit copies of their applications to the cognizant State rehabilitation agency. The State agency may choose to comment or not, and if it does comment, then its concerns are among the factors considered by the Secretary in making the final funding determinations.

[FR Doc. 85-10112 Filed 4-25-85; 8:45 am]

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# Final Register

Friday  
April 26, 1985

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## Part VI

## Department of the Interior

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### Fish and Wildlife Service

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#### 50 CFR Part 17

#### Endangered and Threatened Wildlife and Plants; Final Rules



## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Final Rule To Determine *Erigeron Rhizomatus* To Be a Threatened Species

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** The Service determines a plant, *Erigeron rhizomatus* (rhizome fleabane), to be a threatened species under the authority of the Endangered Species Act of 1973 (Act), as amended. Approximately 20 populations are known, all of which are in New Mexico. The total number of individual plants is only about 200. This species' survival is threatened due to the low number of plants, its restricted distribution, and the potential for habitat loss if uranium mining in the area is ever reactivated. This action implements the protection provided by the Act for this plant.

**DATE:** The effective date of this rule is May 28, 1984.

**ADDRESS:** The complete file for this rule is available for inspection during normal, business hours, by appointment, at the Service's Regional Office of Endangered Species, 500 Gold Avenue, S.W., Room 4000, Albuquerque, New Mexico 87103.

**FOR FURTHER INFORMATION CONTACT:** Peggy Howell, Botanist, Region 2 Endangered Species Staff, see address above (505/766-3972 or FTS 474-3972).

**SUPPLEMENTARY INFORMATION:****Background**

*Erigeron rhizomatus* is in the aster family. The species was first collected in McKinley County, New Mexico, by R.C. Barneby in 1943 and was described by A. Cronquist in 1947. Approximately 20 populations are now known from two counties in New Mexico. Populations are known on the Cibola National Forest in areas south of Fort Wingate in McKinley County, and on the Cibola National Forest and adjacent areas administered by the Bureau of Land Management (BLM) northwest of Datil in Catron County. These are the only areas in which this *Erigeron* has been found.

*Erigeron rhizomatus* is a perennial herb arising from a horizontal underground stem, or rhizome. The leaves are narrow and oblong to linear, up to 1 centimeter (.4 inch) long and 3 millimeters (.12 inch) wide, and dark green. The flower heads are single, 13-

16 millimeters (.5-.6 inch) wide, and blue or white. The stems are in clumps 25-45 centimeters (10-18 inches) high, and up to 30 centimeters (12 inches) across (Martin and Hutchins, 1981).

*Erigeron rhizomatus* grows in a zone of Chinle shale and associated soils in the piñon-juniper association at 2,190 to 2,400 meters (7,180-7,870 feet) elevation. The Zuni Mountain population is found on loose, decaying slopes of the Chinle shale formation. However, the majority of the Datil plants occur in the Baca formation.

Flowering is from May to June. The species appears to be reproducing well, and individuals of all age classes are present. The clumps of plants are all clones. Establishment of new plants by seed is rare, although a large volume of seed is produced (Fletcher, 1978; Sabo, 1981).

Most of the populations are close to inactive uranium claims. If exploration or mining is reactivated, there may be adverse impacts to the plants.

Federal action affecting this species began with Section 12 of the Endangered Species Act of 1973, which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. This report, designated as House Document No. 94-51, was presented to Congress on January 9, 1975. On July 1, 1975, the Service published a notice in the **Federal Register** (40 FR 27823) of its acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) (petition acceptance is now governed by section 4(b)(3)(A)) of the Act, and of its intention thereby to review the status of the plant taxa named therein. On June 16, 1976, the Service published a proposed rule in the **Federal Register** (41 FR 24523) to determine approximately 1,700 vascular plant species to be endangered species pursuant to Section 4 of the Act. This list of 1,700 plant species was assembled on the basis of comments and data received by the Smithsonian Institution and the Service in response to House Document 94-51 and the July 1, 1975, **Federal Register** publication. *Erigeron rhizomatus* was included in the July 1, 1975, notice of review and the June 16, 1976, proposal. General comments received in relation to the 1976 proposal were summarized in the April 26, 1978, **Federal Register** (43 FR 17909).

The Endangered Species Act Amendments of 1978 required that all proposals over 2 years old be withdrawn. A 1-year grace period was given to proposals already over 2 years old. In the December 10, 1979, **Federal**

**Register** (44 FR 70796), the Service published a notice of withdrawal of the June 16, 1976, proposal, along with four other proposals that had expired. *Erigeron rhizomatus*, however, was included in category 1 on the list of plants under review for threatened or endangered classification in the December 15, 1980, **Federal Register** (45 FR 82480). Category 1 refers to taxa for which the Service presently has sufficient information to support the biological appropriateness of their being listed as endangered or threatened species.

The Endangered Species Act Amendments of 1982 required that all petitions pending as of October 13, 1982, be treated as having been newly submitted on that date. The species covered by the December 15, 1980, notice of review were considered to be petitioned, and the deadline for a finding on those species, including *Erigeron rhizomatus*, was October 13, 1983. For *Erigeron rhizomatus*, the petition finding was made on October 13, 1983, that listing was warranted but precluded by pending listing actions in accordance with section 4(b)(3)(B)(iii) of the Act. Such petitions are recycled under section 4(b)(3)(C)(i) of the Act. The Service published a proposed rule to list *Erigeron rhizomatus* as a threatened species on April 24, 1984 (49 FR 17548), constituting the next 1-year finding which would have been required on or before October 13, 1984.

**Summary of Comments and Recommendations**

In the April 24, 1984, proposed rule (49 FR 17548) and associated notifications, all interested parties were requested to submit factual reports or information that might contribute to the development of a final rule. Appropriate State agencies, county governments, Federal agencies, scientific organizations, and other interested parties were contacted and requested to comment. A newspaper notice was published in the *Gallup Independent* and *The Defensor Chieftain* newspapers on May 24, 1984, that invited general public comment. Six comments were received. Summaries of the comments and the Service's response are discussed below. No public hearing was requested or held.

Comments supporting the listing were received from the New York Botanical Garden, the State of New Mexico Natural Resources Department, the International Union for Conservation of Nature and Natural Resources, the Bureau of Land Management (BLM), and the Forest Service.



The National Park Service stated that the proposed listing has no immediate effect upon it, but that, if the plant should be found on National Park Service lands, the Fish and Wildlife Service will be notified.

The BLM informed Service that a population exists on BLM-administered land adjacent to Cibola National Forest northwest of Datil, New Mexico. This information has been added to the rule. The BLM pointed out that it has no information regarding the reactivation of uranium mining claims; however, if the claims were to be resumed, the species would be protected from activities that would jeopardize its existence. The BLM commented that fire may be an additional threat to *Erigeron rhizomatus*. It said it is doubtful that the rhizome fleabane is adapted to fire, and a hot fire in adjacent areas may destroy or damage plants. In addition, it commented that intensive livestock or recreational use could damage the populations and that these activities might have to be regulated. The final rule has been changed to reflect these comments.

The Forest Service, in addition to supporting the listing of *Erigeron rhizomatus* as threatened, provided 1983 survey data. It commented on the number of populations and individual plants. The Service concurs with the Forest Service that it is difficult to define a single plant because *E. rhizomatus* reproduces by rhizomes and grows in clumps. The reproductive biology of this species should be studied to better understand this process. The Forest Service also commented that the Datil plants are found in the Baca formation (rather than the Chinle). This information has been incorporated into the final rule. The Forest Service believes that the only threat to *Erigeron rhizomatus* is the uranium mining potential and that the only other activity that may disturb the rhizome fleabane's habitat is road construction. However, it believes that road construction can be conducted giving full recognition to the plant without significant problems. The Forest Service stated that the eradication of *E. rhizomatus* by disease is unlikely due to the scattered distribution of the plant in two mountain ranges. The rule has been changed to reflect this comment. It also requested that the provision in the Act prohibiting possession of the plant from areas under Federal jurisdiction not be implemented. It stated that it believes that the prohibition of collecting would hamper the verification of distribution information on *Erigeron rhizomatus*. The Service does not agree that section

9(a)(2) of the Act will hamper verification of the species' distribution nor does it agree that this restriction is not necessary. The Act does provide for issuance of a permit for collection of plants for scientific purposes. A permit for collection of *Erigeron rhizomatus* may be obtained from the Service for verification of distribution.

#### Summary of Factors Affecting the Species

After a thorough review and consideration of all available information, the Service has determined that *Erigeron rhizomatus* should be classified as a threatened species. Procedures found as section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations promulgated to implement the listing provisions of the Act (codified at 50 CFR Part 424; as revised to accommodate the 1982 Amendments—See final rule at 49 FR 38900, October 1, 1984) were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. These factors and their application to *Erigeron rhizomatus* Cronquist are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* The main threats to *Erigeron rhizomatus* are from habitat disturbance, especially if there is ever a resumption of uranium mining. Most of the populations in the Datil and Sawtooth Mountains occur within or very close to extensive, currently inactive, uranium claims and could be destroyed or severely damaged if the claims are ever reactivated and developed without planning for the species' protection. Road construction and resulting erosion also could have adverse impacts on *Erigeron rhizomatus* (Fletcher, 1978; Sabo, 1981). The population on BLM-administered land occurs on an allotment under moderate cattle grazing use. Trampling and the subsequent erosion could damage the population and its habitat (L. MacIntosh, BLM, pers. comm., 1984). Recreation, such as incidental camping and hunting, presents a potential threat to the species on BLM land.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* *Erigeron rhizomatus* is not presently desired by plant collectors. Collection for scientific study and threats from overuse are small (Sabo, 1981). However, plants are more vulnerable than animals to taking pressures and because of the low numbers of *Erigeron rhizomatus* and its restricted range, vandalism poses a

threat to the survival of this species.

C. *Disease or predation.* No threat from disease or predation to this species is presently known. The scattered distribution of *Erigeron rhizomatus* reduces its susceptibility to disease. However, if any disease should occur, it might seriously reduce the numbers of the plant.

D. *The inadequacy of existing regulatory mechanisms.* There are no State laws offering protection for *Erigeron rhizomatus*. U.S. Forest Service (USFS) regulations prohibit taking of plants on USFS lands (36 CFR 261.9(b)). These regulations are difficult to enforce in backcountry situations.

E. *Other natural or manmade factors affecting its continued existence.* The limited distribution (two New Mexico counties) and low numbers of plants (approximately 200) make *Erigeron rhizomatus* especially vulnerable to habitat disturbances or other stresses.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to make this rule final. Based on this evaluation, the preferred action is to list *Erigeron rhizomatus* as threatened.

#### Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time a species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for this species at this time. *Erigeron rhizomatus* occurs only on U.S. Forest Service and Bureau of Land Management lands. The Act requires all Federal agencies to carry out programs for the conservation of listed species. The U.S. Forest Service and BLM are aware of where *Erigeron rhizomatus* occurs, and will need to continue to take steps to protect its essential habitat once the species is listed. Also, all Federal agencies, including the U.S. Forest Service and BLM, are bound to avoid any actions that would jeopardize any listed species. Therefore, the determination of critical habitat would not provide any additional benefits for the plants. Critical habitat determinations and publication of detailed maps have the potential of increasing taking pressures or encouraging vandalism. Publication of critical habitat maps for *Erigeron rhizomatus* would enable the public to locate precisely where plants occur, and might lead to vandalism, which could further threaten the species. Because the U.S. Forest Service and BLM know



where *Erigeron rhizomatus* occurs, and will need to continue to protect its habitat, and because a determination of critical habitat might impose further threat to the plants, determination of critical habitat is not considered prudent.

#### Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against taking are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402 and are now under revision (see proposal at 48 FR 29990; June 29, 1983). Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. *Erigeron rhizomatus* is known only from U.S. Forest Service and BLM lands. There are uranium mining claims in the vicinity of the majority of the populations in both the Datil and Sawtooth Mountains. The claims are presently inactive. If exploration or a resumption of mining were to occur, there is potential for Federal involvement.

The Act and its implementing regulations found at 50 CFR 17.71 and 17.72 set forth a series of general trade prohibitions and exceptions that apply to all threatened plant species. With respect to *Erigeron rhizomatus*, all trade prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.71, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, or sell or offer for

sale this species in interstate or foreign commerce. Seeds for cultivated specimens of threatened plant species are exempt from these prohibitions provided that a statement of "cultivated origin" appears on their containers. Certain exceptions can apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened species, under certain circumstances. International and interstate commercial trade in *Erigeron rhizomatus* is not known to exist. It is not anticipated that many trade permits involving plants of wild origin would ever be issued since this plant is not common in the wild and is not presently in cultivation.

Section 9(a)(2)(B) of the Act, as amended in 1982, states that it is unlawful to remove and reduce to possession endangered plant species from areas from Federal jurisdiction. Section 4(d) allows for the provisions of such protection to threatened species through regulations. This protection will apply to *Erigeron rhizomatus* once revised regulations are promulgated. Proposed regulations implementing this prohibition were published on July 8, 1983 (48 FR 31417), and it is anticipated that these will be made final following public comment. *Erigeron rhizomatus* is known only from Federal lands. Requests for copies of the regulations on plants and inquiries regarding them may be addressed to the Federal Wildlife Permit Office, U.S. Fish and Wildlife Service, Washington, D.C. 20240 (703/235-1903).

#### National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined by the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the *Federal Register* on October 25, 1983 (48 FR 49244).

(h) \* \* \*

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
ASTERACEAE—Aster Family:						
<i>Erigeron rhizomatus</i>	Rhizome fleabane	U.S.A. (NM)	T	177	NA	NA

Dated: March 25, 1985.

J. Craig Potter,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 85-10203 Filed 4-25-85; 8:45 am]

BILLING CODE 4310-55-M

#### Literature Cited

- Cronquist, A. 1947. A revision of the North American species of *Erigeron* north of Mexico. *Brittonia* 6:121-302.  
 Fletcher, R. 1978. Status report: *Erigeron rhizomatus*. U.S. Forest Service, Region 3, Albuquerque, New Mexico. 5 pp.  
 Martin, W.C. and Hutchins, C.R. 1981. A Flora of New Mexico. J. Cramer, Germany. xiii + 259 pp.  
 Sabo, D.G. 1981. Status report: *Erigeron rhizomatus*. Office of Endangered Species. U.S. Fish and Wildlife Service, Albuquerque, New Mexico. 16 pp.

#### Authors

The primary authors of this final rule are Peggy Olwell and Alisa Shull. Endangered Species staff, U.S. Fish and Wildlife Service, Department of the Interior, P.O. Box 1306, Albuquerque, New Mexico 87103 (505/766-3972 or FTS 474-3972). Status information and a preliminary listing package were provided by D.G. Sabo, P.O. Box 2267, Albuquerque, New Mexico 87103. E. LaVerne Smith of the Office of Endangered Species served as editor.

#### List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

#### Regulation Promulgation

#### PART 17—[AMENDED]

Accordingly, Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, is amended as set forth below:

1. The authority citation for Part 17 reads as follows:

Authority: Pub. L. 93-205, 87 Stat. 884; Pub. L. 94-359, 90 Stat. 911; Pub. L. 95-632, 92 Stat. 3751; Pub. L. 96-159, 93 Stat. 1225; Pub. L. 97-304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*).

2. Amend § 17.12(h) by adding the following, in alphabetical order, under the family Asteraceae, to the List of Endangered and Threatened Plants:

#### § 17.12 Endangered and threatened plants.

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# Reader Aids

Federal Register

Vol. 50, No. 81

Friday, April 26, 1985

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Indexes	523-5282
Law numbers and dates	523-5282
	523-5266

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#### United States Government Manual

	523-5230
--	----------

#### Other Services

Library	523-4986
Privacy Act Compilation	523-4534
TDD for the deaf	523-5229

## FEDERAL REGISTER PAGES AND DATES, APRIL

12761-12986	1
12987-13160	2
13161-13308	3
13309-13536	4
13537-13750	5
13751-13962	8
13963-14086	9
14087-14206	10
14207-14362	11
14363-14690	12
14691-14918	15
14919-15092	16
15093-15402	17
15403-15534	18
15535-15728	19
15729-15856	22
15857-16048	23
16049-16206	24
16207-16448	25
16449-16682	26

## CFR PARTS AFFECTED DURING APRIL

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

<b>1 CFR</b>	272	13759
<b>Proposed Rules:</b>	273	13759
Ch. III	301	12764, 13178, 13537, 13965, 14087, 15532, 16209
<b>3 CFR</b>	319	14691
<b>Executive Orders:</b>	353	14691
April 17, 1926	400	16218
(Revoked in part by	413	16220
PLO 6599)	418	16053
10000 (Amended	419	16053
by EO 12510)	422	16054
12070 (Superseded	427	16054
by EO 12510)	434	12764
12509	435	12764
12510	436	12765
<b>Proclamations:</b>	905	13761
5164 (Amended by	908	13309
Proc. 5313)	910	13545, 14369, 15537, 16451
5312	911	15097
5313	981	16451
5314	989	14209
5315	1004	16452
5316	1126	12765
5317	1407	12766
5318	1421	16221
5319	1427	16453
5320	1488	13966
5321	1491	13967
5322	1872	12989, 15098, 16055, 16225
5323	1910	16055
5324	1941	16055
5325	1942	12767, 12989, 13004, 15098
5326	1944	12989, 15098, 16055
<b>Administrative Orders:</b>	1945	16055, 16225
<b>Presidential Determinations</b>	1951	12989, 15098, 16225
No. 85-9 of	1955	12989, 15098
March 29, 1985	1962	12989, 15098, 16225
No. 85-10 of	1980	16455
April 2, 1985	3015	14088, 16056
<b>4 CFR</b>		
83	13161	
<b>5 CFR</b>		
307	13172	
316	13172	
352	13963	
930	15407	
1201	13173, 15409	
<b>Proposed Rules:</b>		
293	15158	
870	15428	
871	15428	
872	15428	
873	15428	
<b>7 CFR</b>		
1a	13759	
29	15537	
52	15861	
54	14365	
<b>Proposed Rules:</b>		
Ch. X	13976	
28	16264	
52	13042, 15160, 15568	
400	16502	
402	16090	
430	16225	
800	15569	
915	15430	
925	13609	
929	12812	
944	13609, 15430	
1002	14110	
1004	12813, 14110	
1007	12817	
1011	12817	
1032	13976, 15432	
1046	12817	
1093	12817	
1097	12817	
1098	12817	



1102.....12817	563.....16094, 16271, 16274	460.....13246	511.....14212, 16636
1106.....13977	574.....16274		514.....14212, 16636
1108.....12817	584.....16274	<b>17 CFR</b>	520.....13560, 13561
1150.....14390	589.....16274	4.....15868	558.....13561-13563, 15885,
1421.....16504	611.....14110	140.....15413, 15868	16228
3015.....15433		<b>Proposed Rules:</b>	561.....14096, 14097
<b>8 CFR</b>		33.....14718	570.....14212, 16636
103.....13546, 15098		240.....13388, 13612, 14111,	571.....14212
238.....14369, 16457		15904, 15912, 16302	601.....14212, 16636
		249.....15912	630.....16229
<b>9 CFR</b>		<b>18 CFR</b>	660.....16474
3.....16457		2.....14374, 16076	812.....14212, 16636
78.....13546, 15410		154.....14374	813.....16636
92.....13309, 14919, 16458		157.....14374	861.....16636
327.....14370		201.....14374	1003.....14212
<b>Proposed Rules:</b>		270.....14374, 15729	1010.....13563, 13564, 14212
51.....14246		271.....14374, 14378, 15729	1020.....15543
71.....15166		272.....15729	1030.....13565
78.....15166		273.....15729	<b>Proposed Rules:</b>
85.....14931		375.....15730	74.....16310
92.....13042		385.....15731	101.....13306, 15177, 15458
318.....14711, 15435		<b>Proposed Rules:</b>	182.....12821, 16098
381.....15435		225.....15176	184.....12821, 16098
<b>10 CFR</b>		271.....14249	186.....12821, 16098
2.....13006, 15865		277.....15176	211.....13388
30.....14892		410.....13249	310.....13388
40.....14692		<b>19 CFR</b>	330.....15810
70.....14692		4.....15414	331.....15810
605.....14856		10.....14093	332.....15810
1017.....15818		19.....15884	357.....15810
<b>Proposed Rules:</b>		101.....13190	
19.....13797, 15902		178.....13771	<b>22 CFR</b>
20.....13797, 15902		<b>Proposed Rules:</b>	2.....14379
21.....13797, 15902		6.....12819	120.....12787
30.....13797, 15902		175.....14250	121.....12787
35.....15752		<b>20 CFR</b>	124.....12787
39.....13797, 15902		416.....14211	125.....12787
40.....13797, 15902		629.....16473	126.....12787
50.....13810, 16506		<b>Proposed Rules:</b>	127.....12787
51.....13797, 15902		617.....14720	128.....12787
70.....13797, 15902		635.....14720	<b>Proposed Rules:</b>
71.....13797, 15902		<b>21 CFR</b>	208.....15584
140.....13978		5.....14093, 14094, 14211	501.....16098
150.....13797, 15902		10.....16636	
430.....12966, 13042		25.....16636	<b>23 CFR</b>
<b>11 CFR</b>		71.....14212, 16636	625.....14913
<b>Proposed Rules:</b>		74.....16227	<b>Proposed Rules:</b>
110.....15169		81.....13017, 13018	Ch. I.....16103
<b>12 CFR</b>		105.....13555	625.....16515
5.....13762		107.....13555	635.....14251, 14722
204.....13010		170.....14212, 16636	650.....14251
205.....13180		171.....14212, 16636	655.....16515
208.....13010, 16057		176.....14696	658.....12825, 13821
217.....13010		177.....14095	
225.....16057		178.....13556	<b>24 CFR</b>
226.....13181		179.....15415, 15417	203.....14379
263.....16057		180.....14212	204.....14379
265.....16070		182.....13557	205.....14921
325.....13185		184.....13557, 16080	232.....12788
523.....13968		193.....14096, 14097	235.....12788
531.....16071		201.....14212	570.....12789
552.....16071		310.....14212	595.....12789
563.....16071, 16459		312.....14212, 15543, 16636	882.....15733
571.....16071		314.....14212, 16636	888.....14922, 16229, 16612
612.....15865		330.....14212	<b>Proposed Rules:</b>
721.....16462		430.....14212	207.....15754, 16518
<b>Proposed Rules:</b>		431.....14212	213.....15754
Ch. III.....14247		433.....14212	
352.....15453		444.....15107	<b>25 CFR</b>
546.....16271		448.....15107	700.....14379
552.....16271		510.....14212	
			<b>26 CFR</b>
			1.....13019, 16402
			5c.....13019
			11.....13019



301..... 13019, 14696, 15417	90..... 15734	81..... 15746, 15748, 16476	466..... 15312, 15427
601..... 13020	242b..... 16229	117..... 13456	473..... 15364
602..... 13020, 13962, 14696, 16402	544..... 13771	152..... 16233	474..... 15335
<b>Proposed Rules:</b>	706..... 14384, 14385	158..... 16234	476..... 15347
1..... 13821, 14256, 14392, 15930, 16430	721..... 15891	162..... 16233	489..... 15335
31..... 14392	728..... 15111	180..... 13194, 13195, 14104-14106, 16080-16082	<b>Proposed Rules:</b>
54..... 14392	<b>Proposed Rules:</b>	260..... 14216	435..... 14397
<b>27 CFR</b>	62b..... 13985	261..... 14216	<b>43 CFR</b>
47..... 14380	<b>33 CFR</b>	265..... 16044	255..... 16083
178..... 14380	45..... 13317	266..... 14216	2910..... 16083
250..... 15886	62..... 14213	302..... 13456	<b>Public Land Orders:</b>
275..... 15886	100..... 12799, 14214, 14215, 14701, 15418, 15741, 16230	716..... 16234	2650..... 15546
<b>Proposed Rules:</b>	110..... 15742	723..... 16477	6599..... 12804
9..... 15588	117..... 13318, 14702, 15742	<b>Proposed Rules:</b>	6600..... 15145
<b>28 CFR</b>	146..... 14215	Ch. I..... 15462	6601..... 16235
2..... 12789	150..... 14215	50..... 13130	<b>Proposed Rules:</b>
<b>29 CFR</b>	157..... 12800	51..... 13130	3200..... 14945
2200..... 16474	165..... 14701, 14703, 15419, 15420, 15743, 15744	52..... 13130, 13250, 13390, 14396, 15190, 15761, 15943	3500..... 14512
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	53..... 13130	3510..... 14512
1910..... 14698, 15756	100..... 14257, 14722, 15459, 15760, 16313-16315	58..... 13130	3520..... 14512
1926..... 15756	110..... 12835, 12837, 14723, 14940, 15460	60..... 14941	3530..... 14512
1952..... 14924	117..... 13389, 13835, 14258, 15461	61..... 14941	3540..... 14512
2619..... 14700	165..... 12838	62..... 15186	3550..... 14512
2644..... 12790	<b>34 CFR</b>	65..... 14259, 14396	3560..... 14512
2674..... 12791	350..... 16672	81..... 12840, 13130, 15187, 15463, 15762, 15763	3570..... 14512
2677..... 12796	352..... 16672	152..... 14115	3580..... 14512
<b>Proposed Rules:</b>	358..... 16672	158..... 14115	<b>44 CFR</b>
19..... 13049	359..... 16672	166..... 13251, 13944	64..... 16492
1910..... 12827, 15179	682..... 13916	180..... 13251, 15188, 15189, 16104	80..... 16494
1928..... 15086	<b>36 CFR</b>	220..... 13986	82..... 16494
<b>30 CFR</b>	261..... 16231	227..... 13986	83..... 16494
Ch. VII..... 13566	293..... 16231	228..... 13986, 14336	<b>Proposed Rules:</b>
779..... 16194	294..... 16231	234..... 13986	59..... 14904
780..... 16194	<b>Proposed Rules:</b>	250..... 14076	60..... 14904
783..... 16194	7..... 15056	261..... 16432	61..... 14904, 16236
784..... 16194	Ch. XII..... 15722	264..... 13253	62..... 16236
816..... 16194	<b>37 CFR</b>	271..... 14945	64..... 14904, 14926, 14928
817..... 16194	<b>Proposed Rules:</b>	300..... 14115	66..... 14904
914..... 13566	Ch. IV..... 13524	302..... 13514	67..... 15191
916..... 14212	201..... 14725	704..... 15943	70..... 14904
917..... 13567	<b>38 CFR</b>	712..... 13391	72..... 14904
938..... 13315	17..... 14704	721..... 16519	75..... 14904
948..... 15889	36..... 12800, 13020, 13191, 13970, 16232	761..... 13393	<b>45 CFR</b>
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	<b>41 CFR</b>	701..... 16261
Ch. II..... 15590	1..... 14393, 15848	Ch. 201..... 13023, 13319, 14220, 14386	1321..... 12942
104..... 13617	3..... 15848	101-11..... 15722	1328..... 12942
216..... 12828	19..... 15184	101-20..... 16082	1340..... 14878
700..... 13250	21..... 13836	101-21..... 14242	1611..... 13331
701..... 16311	<b>39 CFR</b>	101-13..... 15722	<b>Proposed Rules:</b>
736..... 16311	111..... 13569, 14216	105-60..... 15722	1301..... 13253
740..... 16311	255..... 14098	105-61..... 15722	1340..... 16105
746..... 16311	<b>Proposed Rules:</b>	105-65..... 15722	<b>46 CFR</b>
750..... 16311	111..... 12839, 13050	<b>Proposed Rules:</b>	76..... 15750
761..... 13250	<b>40 CFR</b>	101-38..... 14260	95..... 15750
772..... 16311	52..... 14925, 15144, 15421-15423, 15745, 15892, 16475	101-39..... 14260	153..... 15895
773..... 13724	60..... 12801-12803, 13021, 15424, 15425, 15544, 15545, 15893	101-40..... 14260	154..... 15895
906..... 16311	61..... 12802, 12803, 13021, 13022, 15386, 15425, 15545	101-41..... 14261, 16316	580..... 14704
915..... 13388	85..... 13970	<b>42 CFR</b>	<b>Proposed Rules:</b>
935..... 12833, 15759	<b>43 CFR</b>	400..... 15312, 15347, 15427	Ch. IV..... 14122
936..... 16518	405..... 15312, 15335, 15427	412..... 15312, 15427	154..... 15591
943..... 14256	420..... 15335	431..... 15312, 15427	159..... 16318
944..... 12834	433..... 15312, 15427	435..... 13196	160..... 16318
<b>31 CFR</b>	436..... 13196	456..... 15312, 15427	175..... 13837
<b>Proposed Rules:</b>	460..... 15312, 15427	462..... 15312, 15427	176..... 13837
10..... 15937	462..... 15312, 15427		177..... 13837
<b>32 CFR</b>			180..... 13837
78..... 14383			181..... 13837
			182..... 13837
			183..... 13837
			184..... 13837
			185..... 13837



186	13837
187	13837
298	13050
516	13617
560	13617
572	13617, 14264

**47 CFR**

Ch. 1	15547
0	14386
2	14386
22	13332, 14386
64	13573
67	15558
69	13023
73	13031-13038, 13333-13337, 13791, 13971, 13972, 15146, 15558, 16084
76	13972
81	13974, 16500
83	16500
90	13596, 14389, 15148
94	13338
95	15563
97	13792

**Proposed Rules:**

Ch. 1	13623, 13986, 13991, 14727, 15191
1	13394
2	13255, 13394, 16109
5	13394
18	13394
21	13394
22	13255, 13394
25	13255
63	16318
67	14729
73	13050, 13394, 13402, 13838, 13994, 14265-14271, 14946-14954, 15591, 16112-16114
76	15592
83	13394
90	13394, 13997
95	13394
97	15195, 15196
99	13394

**48 CFR**

Ch. 4	14196
Ch. 5	14243
Ch. 12	14798
Ch. 19	13200
201	13353
205	13353
206	13353
207	13353
208	13353
210	13353
213	13353
214	13353
215	13353
216	13353
217	13353
219	13353
220	13353
225	13353
235	13353
236	13353
237	13353
245	13353
247	13353
250	13353
252	13353
270	13353
501	14243
507	14243

702	16085, 16086
705	16086
706	16086
714	16086
715	16086
750	16085, 16086
752	16086
1501	14356
1503	14356
1505	14356
1506	14356, 15425
1513	14356
1514	14356
1515	14356, 15425
1517	14356
1527	14356
1533	14356
1536	14356
1552	14356, 15425
1803	13365
1804	13365
1808	13365
1812	13365
1815	13365
1819	13365
1822	13365
1827	13365
1832	13365
1844	13365
1845	13365
1847	13365
1851	13365
1852	13365

**Proposed Rules:**

Ch. 5	14122
52	13256
504	16115
515	15463
516	16115
522	15463
552	15943

**49 CFR**

25	12804
27	13039
107	16089
173	13381
192	13224
195	15895
215	13381
571	15154
1130	15900
1180	15751

**Proposed Rules:**

215	15593
393	14630, 15198
571	13402, 14580, 14589, 14602, 14626
572	14602
575	14400
584	14632
585	14589
1039	14122
1132	13051
1152	13256, 14401
1175	13841
1207	13053
1249	13053

**50 CFR**

10	13708
17	15547, 16680
216	12781
217	12806
219	12781
222	12806

246	12781
258	15901
285	12781
296	13796
301	13382
611	14107, 15425
621	12781
652	14930
671	13040
672	12809, 15426

**Proposed Rules:**

13	15396
17	13054, 14123, 15396, 15764
23	14402
285	13256
611	15464
646	13639
652	16326
683	13405

**LIST OF PUBLIC LAWS**

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List April 23, 1985