States, Reporting and recordkeeping requirements.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

For the reasons set forth above, BEA amends 15 CFR Part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR Part 806 continues to read as follows:

Authority: 5 U.S.C. 301, 22 U.S.C. 3101–3108, and E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12013 (3 CFR, 1977 Comp., p. 147), E.O. 12318 (3 CFR, 1981 Comp., p. 173), and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

§ 806.15 [Amended]

2. Section 806.15(i) is amended as follows:

The exemption level of $10,000,000 in the first sentence is revised to read ''$30,000,000''; in the second sentence, the long form exemption level of $50,000,000 is revised to read ''$100,000,000''; and the short form exemption level ''at least one of the three items exceeds $10,000,000 but no one item exceeds $50,000,000 (positive or negative)'' is revised to read ''at least one of the three items exceeds $30,000,000 but no one item exceeds $100,000,000 (positive or negative).''

[FR Doc. 99–5342 Filed 3–3–99; 8:45 am]

BILLING CODE 3510–06–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Merial, Ltd. The supplemental ANADA provides for use of a larger package size of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, swine, cattle, and sheep for the treatment and control of various bacterial diseases.

EFFECTIVE DATE: March 4, 1999.

FOR FURTHER INFORMATION CONTACT: Patricia D. Leinbach, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6965.

SUPPLEMENTARY INFORMATION: Merial, Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed supplemental ANADA 200–144 that provides for use of a larger package size of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, swine, cattle, and sheep for the treatment and control of various bacterial diseases. The supplemental ANADA is approved as of December 16, 1998, and the regulations are amended in 21 CFR 520.1660d(a) and (b) to reflect the approval.

Furthermore, the regulations had not been previously amended to reflect the sponsor change from Rhone Merieux Canada, Inc., to Merial, Ltd. The regulation in § 520.1660d(b) is amended at this time to reflect the sponsor change.

Approval of this supplemental ANADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary for approval of this supplemental application is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1660d is amended by adding paragraphs (a)(9) and (b)(7), and by revising paragraph (b)(2) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.75 oz; pails: 5 lb).

(b) * * *

(2) No. 017144 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

* * * * *

(7) No. 050604 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

* * * * *

Dated: February 24, 1999.

Woodrow M. Knight,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–5280 Filed 3–3–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 58

[R4–9912; FRL–6237–6]

Modification of the Ozone Monitoring Season for Alabama, Florida, Georgia, Kentucky, Mississippi and Tennessee

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending 40 CFR part 58, appendix D, section 2.5, to lengthen the ozone monitoring season in Alabama, Georgia, Kentucky, Mississippi and Tennessee from April 1 through October 31 to March 1 through October 31; and to shorten the ozone monitoring season for Florida from year round to March 1 through October 31.

EFFECTIVE DATE: This final rule is effective on March 4, 1999.

ADDRESSES: Copies of the material relating to this rule may be examined during normal business hours at the following locations: Environmental Protection Agency, Sam Nunn Atlanta Federal Center, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104; and Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dick Schutt of the EPA Region 4 office at 404/562–9033 or e-mail at ''schutt.dick@epa.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 1998, EPA released a new guidance document concerning ozone monitoring season selection and modification (''Guideline for Selecting and Modifying the Ozone Monitoring Season Based on an 8-Hour Ozone Standard,'' July 9, 1998. EPA–454/R–98–001). This guidance provides a basis

for adjusting the months in which ozone monitoring for the 8-hour ozone National Ambient Air Quality Standard (NAAQS) is required. In the guidance, EPA's Office for Air Quality Planning and Standards (OAQPS) evaluated the ozone monitoring data and seasons for each state, and provided a methodology for calculating new ozone monitoring seasons. On October 6, 1998, EPA Region 4 notified the Region 4 States of EPA's intent to revise the ozone monitoring season. Based on comments received in response to that letter and additional information from OAQPS, EPA Region 4 notified all Region 4 States, on February 18, 1999, of the decision to revise the ozone monitoring season for Alabama, Florida, Georgia, Kentucky, Mississippi and Tennessee and not to change the season for North Carolina and South Carolina. The ozone monitoring season as required by federal regulations can be found in the ''Ozone Monitoring Season by State'' table found in 40 CFR part 58, appendix D, section 2.5. This table is being updated by this action. Since 1990, there has been no exceedance of the 8-hour NAAQS (0.08 ppm) in North Carolina or South Carolina during the months of November through March. Therefore, the ozone monitoring season remains the same for those two States (April 1 through October 31). Since 1990, there has been no exceedance of the 8-hour NAAQS (0.08 ppm) in Alabama, Florida, Georgia, Kentucky, Mississippi, or Tennessee during the months of November through February. Therefore, the monitoring season was shortened for Florida and lengthened for Alabama, Georgia, Kentucky, Mississippi and Tennessee.

II. Summary of Action

EPA is approving a modification to the ozone monitoring season for Alabama, Florida, Georgia, Kentucky, Mississippi, and Tennessee. The ozone monitoring season is being shortened for Florida from year round to March 1-October 31. The season for Alabama, Georgia, Kentucky, Mississippi and Tennessee is being lengthened by one month to March 1-October 31. The season for these five States previously was April 1-October 31. EPA Region 4 is taking this action after reviewing all ambient ozone monitoring data [1] for all Region 4 States over an eight season period.

This rule will be effective March 4, 1999. EPA has determined that today's rule falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedures Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). Today's rule simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs.

Under section 553 of the APA, an agency may find good cause where procedures are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' since the affected parties, the state agencies, have already commented to EPA on this action. Immediate notice in the CFR benefits the public by initiating the ozone monitoring season on March 1, 1999, rather than waiting until the 2000 monitoring season.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under Executive Order 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local or tribal government, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local and tribal governments to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be economically significant as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it is does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities. Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

[1] For this review EPA Region 4 used all available data as entered into EPA's Aerometric Information Retrieval System (AIRS) for the period 1990–1997.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the federal-state relationship under the Clean Air Act, preparation of flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that this approval action does not include a federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves preexisting requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 3, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 58

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements.

Dated: February 24, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Part 58, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 58—[AMENDED]

1. The authority citation for Part 58 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Part 58, Appendix D, section 2.5: the table is amended by revising the entries for Alabama, Florida, Georgia, Mississippi and Tennessee to read as follows:

Appendix D to Part 58—Network Design for State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS), and Photochemical Assessment Monitoring Stations (PAMS)

* * * * *

2.5 Ozone (O3) Design Criteria for SLAMS

* * *

OZONE MONITORING SEASON BY STATE

State	Begin month	End month
* * * * *		
Alabama	March	October.
* * * * *		
Florida	March	October.
Georgia	March	October.
* * * * *		
Kentucky	March	October.
* * * * *		
Mississippi	March	October.
* * * * *		
Tennessee	March	October.
* * * * *		

[FR Doc. 99–5382 Filed 3–3–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136 and 439

[FRL–6304–8]

RIN 2040–AA13

Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction

SUMMARY: EPA is correcting minor errors in the preamble and effluent limitations guidelines and standards for the pharmaceutical manufacturing point source category, which appeared in the **Federal Register** on September 21, 1998 (63 FR 50388).

EFFECTIVE DATE: These corrections shall become effective March 4, 1999. In accordance with 40 CFR 232, this rule will be considered promulgated for purposes of judicial review at 1:00 P.M. Eastern time on March 18, 1999.