Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revoke's the 700 foot Class E airspace at Newgulf, TX. The cancellation of the VOR/DME A, SIAP serving the Newgulf Airport, Newgulf, TX, has prompted this action. Additionally, the Newgulf Airport, was officially closed December 31, 1993. Class E airspace extending upward from 700 feet above ground level (AGL) is no longer needed to contain IFR operations at Newgulf, TX.

Since this action merely involves the revocation of Class E airspace as a result of the airport closure and cancellation of a SIAP, notice and public procedure under 5 U.S.C. 553(b) are unnecessary. The Class E airspace must be removed to avoid confusion on the part of the pilots flying in the vicinity of the closed Newgulf airport, and to promote the safe and efficient handling of air traffic in the area. Therefore, I find that notice and public procedure under 5 U.S.C. 553 are unnecessary and good cause exists for making this amendment effective in less than thirty days.

The FAA has determined that this regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore (1) is not a ''significant regulatory action'' under Executive Order 12866; (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 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, *Airspace Designations and Reporting Points,* dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace extending upward from 700 feet above the surface.

* * * * *

ASW TX E5 Newgulf, TX [Revoke]

* * * * *

Issued in Fort Worth, TX, on July 17, 1995.

Albert L. Viselli,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 95–18592 Filed 7–27–95; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Final Rule: Requirements for Child-Resistant Packaging; Packages Containing 250 mg or More of Naproxen

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a rule to require child-resistant packaging for naproxen preparations containing 250 mg or more of naproxen per retail package. Naproxen is marketed as an anti-inflammatory drug. It is used to treat various forms of arthritis, mild to moderate pain, and menstrual pain. The Commission has determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from ingesting naproxen. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: The rule will become effective on February 6, 1996, and applies to naproxen preparations packaged on or after that date.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400 ext. 1368.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, authorizes the Commission to establish standards for the ''special packaging'' of any household substance if (1) The degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance.

Special packaging, also referred to as ''child-resistant (CR) packaging,'' is packaging that (1) Is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) is not difficult for ''normal adults'' to use properly. 15 U.S.C. 1471(4). Household substances for which the Commission may require CR packaging include (among other categories) foods, drugs, or cosmetics as these terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). 15 U.S.C. 1471(2)(B). The Commission has performance requirements for special packaging. 16 CFR 1700.15, 1700.20.

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: ''This package for households without young children.'' 15 U.S.C. 1473(a).

2. Naproxen

Naproxen is a nonsteroidal anti-inflammatory drug (''NSAID''). This class of compounds is used to treat various forms of arthritis, mild to moderate pain, and menstrual pain. As discussed below, the Commission is aware of many reports of poisoning incidents involving naproxen in children under 5 years old.

Until recently, naproxen was a prescription drug that was required to be in child-resistant packaging by the

Commission's regulation of human oral prescription drugs, 16 CFR 1700.14(a)(10). By a letter dated January 11, 1994, the Food and Drug Administration (''FDA'') granted nonprescription (''over-the-counter,'' or ''OTC'') status to the sodium salt of naproxen.

The patent for naproxen expired in 1993. The OTC naproxen product approved by the FDA is currently manufactured by the original patent holder and marketed by another company as a joint venture. In accordance with FDA's regulations, these two companies have sole marketing rights until January 11, 1997. Currently, the companies are voluntarily placing naproxen in CR packaging.

The OTC formulation of naproxen consists of naproxen sodium and is equivalent to 200 mg of naproxen and 20 mg of sodium per tablet. The recommended dose is 1 tablet every 8 to 12 hours. The maximum daily dose is 3 tablets for patients between the ages of 12 and 65 and 2 tablets for those over 65. The drug is not recommended for children under 12 years old except under the supervision of a doctor. However, naproxen is used to treat juvenile arthritis in children over 2 years.(5) [1]

Although the current marketers are voluntarily placing naproxen in child-resistant packaging, a mandatory special packaging standard for naproxen products would ensure that other companies that may market such products in the future would use CR packaging. As discussed below, an increased incidence of accidental ingestions by children under 5 involving ibuprofen (another NSAID) after it became available OTC, supports this action. A mandatory standard would also enable the Commission to ensure that the packaging used meets the performance requirements of the PPPA test protocol at 16 CFR 1700.15, 1700.20.

3. The Proposed Rule

On November 14, 1994, the Commission issued a proposed rule that would require CR packaging for OTC drugs containing the equivalent of 250 mg or more of naproxen. 59 FR 56445. As discussed below, the Commission received 4 comments in response to the proposed rule. All were in favor of issuing the rule.

The Commission also received a request to extend the comment period from Syntex Corporation (''Syntex''), one of the companies involved in the joint venture for temporary exclusive marketing rights for naproxen. Syntex stated that it needed additional time to prepare a response to the proposed rule since it had recently been acquired by Roche. The Commission granted the request for an extension of time. 60 FR 2716 (January 11, 1995). However, the Commission did not subsequently receive any comments from Syntex.

B. Toxicity of Naproxen

The Commission's Directorate for Health Sciences reviewed the toxicity of naproxen. Side effects commonly associated with naproxen and other NSAID's include dose-related gastrointestinal (GI) complications such as constipation, heartburn, abdominal pain, nausea, and diarrhea. Other adverse effects include headache, dizziness, drowsiness, pruritus (itching), and tinnitus (ringing in the ears).(5)

Naproxen may also cause liver and kidney toxicity, but these effects are infrequent with routine therapeutic use. Kidney toxicity has been documented in children following naproxen therapy. One report describes a two-year-old male with juvenile arthritis who developed acute renal failure and hyperkalemia (high blood potassium) following treatment with 20 mg/kg/day of naproxen sodium for 1 month.(5)

Acute overdosage of naproxen may result in mild, transient effects, including drowsiness, GI disturbances, and prolonged clotting times. Life-threatening effects are uncommon, but serious complications such as seizures, apnea (cessation of breathing), metabolic acidosis (reduced blood pH), and impaired kidney function have been documented. The acute lethal dose of naproxen is unknown and the severity of symptoms is not always dose-related.(5)

The Commission's Directorate for Epidemiology reviewed data from the National Electronic Injury Surveillance System (''NEISS'') involving hospital emergency room treatment of children under 5 years old who ingested naproxen. NEISS is a probability sample based on hospital emergency rooms nationwide. There were nine reported cases from 1980 to 1989 and 26 reported cases from 1990 to 1994. The average annual number of estimated cases during these time periods was 50 and 260, respectively. In 1982, one case resulted in the hospitalization of a 2-year-old male. In 1994, the Commission had reports of three emergency room cases, each involving a 2-year-old child who was examined or treated and released following ingestion of naproxen.(7)

The Commission's Directorate for Health Sciences requested 1993 incident data from the American Association of Poison Control Centers (''AAPCC'') related specifically to naproxen in children under 5 years old. (AAPCC data from 1985 to 1992 were unavailable because naproxen poisoning incidents were not categorized separately from other NSAID incidents unless they resulted in death.) Of the 1,413 naproxen ingestions reported for 1993, two resulted in outcomes characterized by AAPCC as ''moderate,'' i.e., pronounced and prolonged symptoms that generally require treatment but are not life-threatening. In addition, 53 of the ingestions resulted in outcomes characterized by AAPCC as ''minor,'' i.e., symptoms present, but mild with rapid and complete resolution. Forty-eight cases were documented as potentially toxic, but the ultimate disposition was not reported. From 1985 to 1993, there were no naproxen-related fatalities in children reported to the AAPCC.(5)

Several cases of naproxen poisoning in children were reported through the FDA's Adverse Reactions Reporting System (''ARRS'') and the Worldwide Safety Surveillance and Reporting division of Syntex, the manufacturer of naproxen. These include: An 8-month-old girl who died following daily treatment for fever and an upper respiratory tract infection with 100 to 400 mg naproxen sodium for 5 days; a 2-year-old boy who recovered after developing drowsiness, ataxia (loss of voluntary muscle coordination), and a prolonged bleeding time following ingestion of naproxen (up to 2 grams), hydrogen peroxide, and eucalyptus oil; a 2-year-old girl who suffered dyspepsia (indigestion) after ingesting 625 mg of naproxen; and a 5-year-old girl who developed convulsions after she accidently ingested an unknown amount of naproxen sodium.(5)

NEISS data for ingestions of ibuprofen, another popular NSAID that began to be marketed OTC in 1984, show that there was a larger estimated number of children under 5 years old treated in hospital emergency rooms for each year from 1984–1994 after ibuprofen was granted OTC status, than for each year from 1980–1983.(7)

Most cases of naproxen poisoning described in the literature involve adults. These patients generally developed GI side effects and several experienced seizures. The incidence of side effects may differ in children and adults. Studies involving children taking naproxen showed that, compared to adults, the children's incidence of: rash and prolonged bleeding times were

[1] Numbers in parentheses refer to documents at the end of this notice.

increased; GI and central nervous system (CNS) reactions were similar; and other reactions decreased.(5)

The relevant literature shows that naproxen and other NSAID's have adverse fetal effects when used during pregnancy. A newborn delivered 8 hours after his mother ingested an overdose of 5 grams of naproxen developed severe hyponatremia (low blood sodium) and water retention with indications of cerebral irritation and paralytic ileus. It was tentatively diagnosed that naproxen adversely affected renal function. Complications were reported in three newborns after maternal naproxen treatment to prevent premature labor. One newborn died, and the autopsy showed a brain hemorrhage, multiple gastric ulcers, extensive GI bleeding, and a cardiovascular birth defect that is a known adverse effect of NSAID's. A 7-day-old breast-fed infant boy developed symptoms associated with naproxen toxicity after his mother was treated with 1 g naproxen and 800 mg of antibiotic for 3 days.(5)

C. Level for Regulation

The Commission is issuing a rule that requires special packaging for OTC naproxen products containing the equivalent of 250 mg or more naproxen per retail package. This level is based on established guidelines for medical treatment following ingestion of NSAID's. It is also based on a known toxic dose of naproxen, reduced by a safety factor to account for biologic variability. (5 and 10)

The precise toxic level of naproxen in humans is unknown. However, guidelines established for pediatric NSAID overdose suggest medical treatment for young children who ingest five times the maximum single therapeutic dose. Therefore, the dose of naproxen requiring medical intervention would be 5 mg/kg (the maximum single therapeutic dose) times five, or 25 mg/kg. In a 10-kg child, this is equivalent to 250 mg of naproxen, or one and one-quarter OTC tablets. (5 and 10)

The same level results when calculated using a different approach. When treatment information for poisonings is unavailable, the staff typically uses a known toxic dose divided by a safety factor of 10 to determine the level for regulation. Applying this factor to the 250 mg/kg dose of naproxen that caused life-threatening acidosis in a 15-year-old girl also results in a level of 25 mg/kg, or 250 mg in a 10-kg child. (5 and 10)

The Commission emphasizes that the 250 mg level applies to the total amount of the product sold at retail in a single package, regardless of whether the contents of the package are loose or also packaged in non child-resistant envelopes or strip packages. In administering the PPPA regulations for acetaminophen, iron-containing preparations and ibuprofen, the Commission has encountered instances in which product manufacturers package one or two tablets in individual envelopes for sale to consumers seeking medication for immediate use. Because each envelope is an individual retail unit and contains less than the amount of ibuprofen or acetaminophen subject to regulation, the envelopes need not be child-resistant.

However, the Commission has also encountered instances in which repackagers have packaged multiple non child-resistant envelopes of acetaminophen, iron, or ibuprofen in outer blister packs or clamshell packages that contain a total quantity of these products in excess of the regulatory minimum, but that are also not child-resistant. We note that the regulatory minimum contained in a ''single package'' refers to the total contents of the retail package, not the contents of each individual envelope. To avoid future confusion on this issue, this regulation refers to the contents of the ''retail package'' to clarify that whether a product requires child-resistant packaging is based on the total amount of naproxen packaged for sale at retail.

D. Comments on the Proposed Rule

The Commission received four comments responding to the proposed rule. These came from the American Society of Health-System Pharmacists, the National Association of Pediatric Nurse Associates and Practitioners, and two groups of university students. All agreed that the Commission should require CR packaging for naproxen. In addition, the students argued for an effective date shorter than the 180-day period proposed by the Commission. One group of students advocated a 90-day effective date. The argument for the shorter date was that the companies with exclusive marketing rights are voluntarily using CR packaging now.

The Commission does not agree that a shorter effective date is necessary. In general, the PPPA requires at least 180 days before a regulation takes effect. 15 U.S.C. 1471n. As explained in section F below, the Commission does not believe that a shorter period is justified in this case.

E. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning children's ingestion of naproxen sodium demonstrate that this compound can cause serious illness and injury to children. Moreover, the preparations are readily available to children.(5) The Commission concludes that a regulation is needed to ensure that products subject to the regulation will be placed in CR packaging by any new manufacturers. In addition, the regulation will enable the Commission to enforce the CR packaging requirement and ensure that effective CR packaging is used.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that the degree and nature of the hazard to children from ingesting naproxen is such that special packaging is required to protect children from serious illness. The Commission bases this finding on the toxic nature of these products, described above, and their accessibility to children in the home.

2. Technical Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission is required to find that the special packaging is ''technically feasible, practicable, and appropriate.'' 15 U.S.C. 1472(a)(2). Technical feasibility may be found when technology exists or can be readily developed and implemented by the effective date to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use. (9)

The current marketers of OTC naproxen use packaging that not only is child resistant, but also is easier for adult consumers to open. Therefore, the Commission concludes that CR packaging for naproxen is technically feasible, practicable, and appropriate.

3. Other Considerations

In establishing a special packaging standard under the PPPA, the Commission must consider the following:

a. The reasonableness of the standard;

b. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

c. The manufacturing practices of industries affected by the PPPA; and

d. The nature and use of the household substance. 15 U.S.C. 1472(b).

The Commission has considered these items with respect to the various determinations made in this notice, and finds no reason to conclude that the rule is unreasonable.

F. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n.

The Commission does not believe that a shorter effective date is necessary to protect the public interest. Naproxen is currently sold in CR packaging by the companies that have exclusive marketing rights until January 11, 1997. The Commission does not have any indication that significant quantities of naproxen will be marketed in non-CR packaging before a 180 day effective date, with the possible exception of a single size non-CR package as allowed under the PPPA. Thus, the Commission finds that a 180 day effective date is consistent with the public interest. The final rule will apply to products that are packaged on or after the effective date.

G. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

For the proposed rule, the Commission's Directorate for Economics prepared a preliminary economic assessment of a rule to require special packaging for naproxen preparations with 250 mg or more of naproxen in a single package. Based on this assessment, the Commission concluded that such a requirement would not have a significant impact on a substantial number of small businesses or other small entities because the current marketers of naproxen are already using CR packaging and have sole marketing rights for 3 years. Furthermore, the relatively low costs of CR packages should not be an entry burden for future marketers. The Commission received no comments on its preliminary analysis and is not aware of any changes that would affect the Commission's previous conclusion. Thus, the Commission concludes that the rule to require special packaging for naproxen preparations having 250 mg or more of naproxen would not have any significant economic effect on a substantial number of small entities. (8)

H. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the PPPA requirements for naproxen preparations.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). In connection with the proposed rule, the Commission determined that CR packages for naproxen preparations would have no significant effects on the environment. The Commission is unaware of any developments to change this preliminary assessment. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required. (8)

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, 16 CFR part 1700 is amended as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by republishing paragraph (a) introductory text and adding new paragraph (a)(25), to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(25) *Naproxen.* Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

Dated: July 24, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

(**Note.** This list of relevant documents will not be printed in the Code of Federal Regulations.)

1. Vale, J.A. and Meredith, T.J., Acute poisoning due to non-steroidal anti-inflammatory drugs: clinical features and management. Medical Toxicology 1:12–31, 1986.

2. Memorandum from Terry Kissinger, Ph.D., EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Injury Data on Naproxen and Ibuprofen for the 1980–1993 Period,'' May 27, 1994.

3. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Proposal to Require Child-Resistant Packaging for OTC Preparations Containing Naproxen,'' June 7, 1994.

4. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Preliminary Assessment of Economic and Environmental Effects of a Proposal to Require Child-Resistant Packaging,'' September 28, 1994.

5. Memorandum from Sandra Inkster, Ph.D., HSHE, to Jacqueline Ferrante, Ph.D., HSPS, ''Review of Naproxen Toxicity,'' July 17, 1994.

6. Briefing memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Proposed Special Packaging Standard for Naproxen,'' September 29, 1994.

7. Memorandum from Terry Kissinger, Ph.D., EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Update of Injury Data Involving Naproxen and Ibuprofen,'' May 4, 1995.

8. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Final Regulatory Flexibility Act Analysis: Child-Resistant Packaging for OTC Packages Containing 250 mg or more of Naproxen,'' June 12, 1995.

9. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Child-Resistant Packaging for OTC Preparations Containing Naproxen,'' May 4, 1995.

10. Briefing memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Final Special Packaging Standard for Naproxen,'' June 29, 1995.

[FR Doc. 95–18504 Filed 7–27–95; 8:45 am]
BILLING CODE 6355–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 901 and 924

Alabama and Mississippi Regulatory Programs

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Notice of decision.

SUMMARY: OSM is announcing its decision on initial enforcement of underground coal mine subsidence control and water replacement requirements in Alabama and Mississippi. Amendments to the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and the implementing Federal regulations require that underground coal mining operations conducted after October 24, 1992: Promptly repair or compensate for subsidence-caused material damaged to noncommercial buildings and to occupied dwellings and related structures and promptly replace drinking, domestic, and residential water supplies that have been adversely affected by underground coal mining. After consultation with Alabama and Mississippi and consideration of public comments, OSM has decided that initial enforcement in Alabama will be accomplished through State and OSM enforcement and that initial enforcement is not reasonably likely to be required in Mississippi and therefore implementation in that State will be accomplished through the State program amendment process.

EFFECTIVE DATE: July 28, 1995.

FOR FURTHER INFORMATION CONTACT: Jesse Jackson, Jr., Field Office Director, Birmingham Field Office, OSM, 135 Gemini Circle, Suite 215, Birmingham, Alabama, 35209, Telephone: (205) 290–7287.

SUPPLEMENTARY INFORMATION:

A. The Energy Policy Act

Section 2504 of the Energy Policy Act of 1992, Pub. L. 102–486, 106 Stat. 2776 (1992) added new section 720 to SMCRA. Section 720(a)(1) requires that all underground coal mining operations promptly repair or compensate for subsidence-caused material damage to noncommercial buildings and to occupied residential dwellings and related structures. Repair of damage includes rehabilitation, restoration, or replacement of the structures identified in section 720(a)(1), and compensation must be provided to the owner in the full amount of the reduction in value of the damaged structures as a result of subsidence. Section 720(a)(2) requires prompt replacement of certain identified water supplies if those supplies have been adversely affected by underground coal mining operations.

These provisions requiring prompt repair or compensation for damage to structures, and prompt replacement of water supplies, went into effect upon passage of the Energy Policy Act on October 24, 1992. As a result, underground coal mine permittees in States with OSM-approved regulatory programs are required to comply with these provisions for operations conducted after October 24, 1992.

B. The Federal Regulations Implementing the Energy Policy Act

On March 31, 1995, OSM promulgated regulations at 30 CFR part 817 to implement the performance standards of section 720(a) (1) and (2) of SMCRA (60 FR 16722).

30 CFR 817.121(c)(2) requires in part that:

> The permittee must promptly repair, or compensate the owner for, material damage resulting from subsidence caused to any non-commercial building or occupied residential dwelling or structure related thereto that existed at the time of mining. * * * The requirements of this paragraph apply only to subsidence-related damage caused by underground mining activities conducted after October 24, 1992.

30 CFR 817.41(j) requires in part that:

> The permittee must promptly replace any drinking, domestic or residential water supply that is contaminated, diminished or interrupted by underground mining activities conducted after October 24, 1992, if the affected well or spring was in existence before the date the regulatory authority received the permit application for the activities causing the loss, contamination or interruption.

Alternative OSM enforcement decisions. 30 CFR 843.25 provides that by July 31, 1995, OSM will decide, in consultation with each State regulatory authority with an approved program, how enforcement of the new requirements will be accomplished. As discussed in the April 10, 1995, **Federal Register** (60 FR 18044) and as reiterated below, enforcement could be accomplished by State, OSM, or joint State and OSM enforcement of the requirements, or by a State after it has amended its program.

(1) *State program amendment process.* If the State's promulgation of regulatory provisions that are counterpart to 30 CFR 817.41(j) and 817.121(c)(2) is imminent, the number and extent of underground mines that have operated in the State since October 24, 1992, is low, the number of complaints in the State concerning section 720 of SMCRA is low, or the State's investigation of subsidence-related complaints has been thorough and complete so as to assure prompt remedial action, than OSM could decide not to directly enforce the Federal provisions in the State. In this situation, the State would enforce its State statutory and regulatory provisions once it has amended its program to be in accordance with the revised SMCRA and to be consistent with the revised Federal regulations. This program revision process, which is addressed in the Federal regulations at 30 CFR Part 732, is commonly referred to as the State program amendment process.

(2) *State enforcement.* If the State has statutory or regulatory provisions in place that correspond to all of the requirements of the above-described Federal regulations at 30 CFR 817.41(j) and 817.121(c)(2) and the State has authority to implement its statutory and regulatory provisions for all underground mining activities conducted after October 24, 1992, then the State would enforce its provisions for these operations.

(3) *Interim direct OSM enforcement.* If the State does not have any statutory or regulatory provisions in place that correspond to the requirements of the Federal regulations at 30 CFR 817.41(j) and 817.121(c)(2), then OSM would enforce in their entirety 30 CFR 817.41(j) and 817.121(c)(2) for all underground mining activities conducted in the State after October 24, 1992.

(4) *State and OSM enforcement.* If the State has statutory or regulatory provisions in place that correspond to some but not all of the requirements of the Federal regulations at 30 CFR 817.41(j) and 817.121(c)(2) and the State has authority to implement its provisions for all underground mining activities conducted after October 24, 1992, then the State would enforce its provisions for these operations. OSM would then enforce those provisions of 30 CFR 817.41(j) and 817.121(c)(2) that are not covered by the State provisions for these operations.

If the State has statutory or regulatory provisions in place that correspond to some but not all of the requirements of the Federal regulations at 30 CFR 817.41(j) and 817.121(c)(2) and if the State's authority to enforce its provisions applies to operations conducted on or after some date later than October 24, 1992, the State would enforce its provisions for these operations on and after the provisions' effective date. OSM would then enforce 30 CFR 817.41(j) and 817.121(c)(2) to the extent the State statutory and regulatory provisions do not include corresponding provisions applicable to all underground mining activities conducted after October 24, 1992; and OSM would enforce those provisions of 30 CFR 817.41(j) and 817.121(c)(2) that are included in the