Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, Operations Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–AWP–30.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Operations Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Operations Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace area at Victorville, CA. The closure of George Air Force Base has made this proposal necessary. The intended effect of this proposal is to redefine the controlled airspace necessary for IFR operations at Southern California International Airport, Victorville, CA. Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996 and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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 10034; 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 proposed rule would 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).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation administration proposes to amend 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. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E Airspace

* * * * *

AWP CA E Victorville, CA [Revised]

Victorville, Southern California International Airport, CA
(Lat. 34°35.67′N, long. 117°22.93'W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the Victorville, Southern California International Airport, CA.

* * * * *

Issued in Los Angeles, California, on November 4, 1996.

Sabra W. Kaulia,

Assistant Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–29683 Filed 11–19–96; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Proposed Rule: Requirements for Child-Resistant Packaging; Packages Containing More Than 50 mg of Ketoprofen

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing a rule to require child-resistant packaging for ketoprofen preparations containing more than 50 mg of ketoprofen per retail package. Ketoprofen is a nonsteroidal anti-inflammatory drug and is used to relieve minor aches and pains and to reduce fever. The Commission has preliminarily 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 ketoprofen. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: Comments on the proposal should be submitted no later than February 3, 1997.

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502,

4330 East-West Highway, Bethesda, Maryland 20814–4408, telephone (301) 504–0800.

FOR FURTHER INFORMATION CONTACT: Jacqueline Ferrante, Ph.D., Division of Poison Control and Scientific Coordination, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0477 ext. 1199.

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), 16 CFR 1700.5.

2. Ketoprofen

Ketoprofen is a nonsteroidal anti-inflammatory drug (''NSAID''). This class of compounds also includes ibuprofen and naproxen. Ketoprofen is used to relieve minor aches and pains such as those associated with colds, toothaches, menstrual cramps, and muscular aches. It is also used to reduce fever.[2] [1]

For the past ten years, ketoprofen has been a prescription drug. Like all prescription drugs, it was required to be in child-resistant packaging by the Commission's regulation of human oral prescription drugs, 16 CFR 1700.14(a)(10). The U.S. patent on ketoprofen expired in 1993. On October 6, 1995, the Food and Drug Administration (''FDA'') granted nonprescription (''over-the-counter,'' or ''OTC'') status to ketoprofen. [2]

The OTC formulations, ketoprofen and ketoprofen tartrazine, contain 12.5 milligrams (mg) of ketoprofen per dose. The recommended dose is 1 tablet every 4 to 6 hours. The maximum daily dose is 6 tablets. The drug is not recommended for children under 16 years old except under the supervision of a doctor. OTC ketoprofen should not be used (1) with any other analgesic or anti-pyretic, (2) for more than 3 days for fever, (3) for more than 10 days for pain, or (4) during the last trimester of pregnancy unless directed by a physician. [2]

3. Special Packaging

The current marketers are voluntarily placing ketoprofen in child-resistant packaging. However, a mandatory special packaging standard for ketoprofen products would ensure that other companies that may market such products in the future would use CR packaging.

Two other NSAIDs that previously became available OTC are ibuprofen and naproxen. After ibuprofen was introduced OTC, there was an increased incidence of accidental ingestions of the drug by children under 5. [2]

In part to avoid a similar experience with naproxen, in 1995, the Commission then issued a rule requiring CR packaging for naproxen preparations containing 250 mg or more per retail package. 60 FR 38671. The rule became effective February 6, 1996. Similar reasoning applies to ketoprofen.

A mandatory standard for ketoprofen 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.

B. Toxicity of Ketoprofen

The Commission's Directorate for Epidemiology and Health Sciences reviewed the toxicity of ketoprofen. Side effects commonly associated with ketoprofen, as with other NSAID's, are gastrointestinal (GI) complications. These include nausea, vomiting, diarrhea, constipation, heartburn, and abdominal pain. Other common adverse effects include headache, dizziness, visual disturbances, rash, and hypersensitivity reactions.[2]

Ketoprofen may also cause more severe adverse GI effects, such as gastric or duodenal ulcer with bleeding or perforation; intestinal ulcers; ulcerative stomatitis or colitis; gingival ulcer; perforation and hemorrhage of the esophagus, stomach, small or large intestine; hematemesis; and rectal bleeding. Renal injuries also may result from chronic use of ketoprofen.[2]

The staff reviewed the relevant medical literature which cites several cases of severe adverse reactions to ketoprofen administration. In one case, a 61 year old woman suffered acute renal failure after taking 400 mg of ketoprofen daily for 10 days. She recovered after peritoneal dialysis. In addition, the literature reports one case of pancreatitis after 12 days of ketoprofen therapy and two cases of ketoprofen induced hepatitis. Other cases reported in the literature involved co-ingestion of other substances.[2]

The FDA maintains a data base known as the Adverse Events Reporting System (''AERS'') for reports of adverse reactions detected after marketing a drug or biological product. Drug manufacturers are required to report to the FDA any known adverse effects associated with their products, but only an estimated 1% of all adverse reactions are actually reported. Also, reports may reflect effects from an underlying disease process or a reaction to multiple drugs. Of the 903 ketoprofen-associated cases reported to the FDA between 1986 and October 1995, the most common adverse reactions were abdominal pain (122), diarrhea (87), nausea (82), GI hemorrhage (70), rash (55), indigestion (39), labored breathing (34), allergic reaction (30), dizziness (30), and hives (30).[2]

Among the ketoprofen cases in the AERS database are 51 more serious reactions, i.e., hospitalizations, reactions resulting in permanent disability, or deaths. Five of these involved children under 16 years of age. Three 15 year old children required hospitalization for severe renal injury, and one 15 year old suffered a life-threatening GI hemorrhage and perforation. These events followed 10–18 days of therapy with daily doses of 200–225 mg ketoprofen. A 10 year old also required hospitalization for severe

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

vision abnormalities after 15 days of treatment with 150 mg ketoprofen.[2]

The medical literature reports 2 overdoses, both involving other substances as well. In one case, a 12 year old girl ingested an unknown amount of ketoprofen plus 12 hydrocodone/acetaminophen tablets. She developed tonic-clonic seizures with loss of consciousness and metabolic acidosis. The symptoms resolved within 2 hours and she recovered fully. In the other incident, an adult ingested 12 capsules of sustained release ketoprofen 200 mg (total=2.4 grams) with 375 milliliters (12.5 ounces) of vodka. Only mild effects resulted since the victim vomited within 1 hour of the ingestion.[2]

The AERS database reports no pediatric ketoprofen overdoses, but there were some incidents involving adults. One intentional overdose of 1,000 mg ketoprofen resulted in moderate to severe kidney injury (kidney pain, bloody urine, increase creatinine levels). Ingestion of 500 mg of ketoprofen plus an unknown amount of ciprofloxacin produced death in a 50 year old woman. The symptoms which included GI hemorrhage, thrombocytopenia, coagulation disorders, and decreased prothrombin, were most likely related to ketoprofen.[2]

The AERS system also reports two neonatal poisoning cases in which the mothers took ketoprofen at some point in their pregnancy. One infant died shortly after birth from acute renal failure. In the second case (which involved multiple medications) twins developed acute renal failure shortly after birth. One twin died and the other recovered but was neurologically impaired.[2]

The staff reviewed accidental ingestion data for children under age 5. The American Association of Poison Control Center (''AAPCC'') collects incident data through its Toxic Exposure Surveillance System (''TESS'') which covers incidents from 1985 to 1994. Poisoning incidents involving ketoprofen are not recorded separately from other NSAIDs unless they were fatal. No deaths involving ketoprofen were reported during this period.[2]

CPSC's data base, the National Electronic Injury Surveillance System (''NEISS'') monitors emergency room visits to selected hospitals throughout the United States. Review of NEISS data from 1988 to June 1996 shows three cases involving ketoprofen and children under 5 years old. All three incidents occurred in 1996. None were fatal or required hospitalization.[2]

C. Level for Regulation

The Commission is proposing a rule that requires special packaging for OTC ketoprofen products containing more than 50 mg ketoprofen per retail package. This level is based on established guidelines for medical treatment following pediatric ingestion of NSAID's.[5] These guidelines suggest medical treatment for young children who ingest five times the maximum single therapeutic dose. For ketoprofen, the maximum single therapeutic dose is 75 mg or 1.08 mg/kg assuming an average adult weight of 70 kg. The dose of ketoprofen requiring medical intervention would be five times 1.08 mg/kg, which in a 10-kg child would be more than 50 mg of ketoprofen, or four OTC tablets.[2]

D. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning children's ingestion of ketoprofen demonstrate that this compound can cause serious illness and injury to children. Moreover, the preparations are readily available to children. The Commission preliminarily 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 preliminarily finds that the degree and nature of the hazard to children from ingesting ketoprofen 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.[4]

The current marketers of OTC ketoprofen voluntarily use packaging that is child resistant. Similar designs have been shown to meet the revised testing protocol for senior adult use effectiveness. Therefore, the Commission concludes that CR packaging for ketoprofen is technically feasible, practicable, and appropriate.[3]

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 factors with respect to the various determinations made in this notice, and preliminarily finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

E. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final 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. The companies that are currently marketing ketoprofen are voluntarily using CR packaging. The Commission does not have any indication that significant quantities of ketoprofen will be marketed in non-CR packaging before a 180 day effective date, except for 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 and proposes that a final rule would take effect 180 days after publication of the final rule. A final rule would apply to products that are packaged on or after the effective date.

F. 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.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to require special packaging for ketoprofen preparations with more than 50 mg ketoprofen in a single package. Based on this assessment, the Commission concludes 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 ketoprofen are using CR packaging. Furthermore, the relatively low costs of CR packages should not be an entry burden for future marketers.

G. 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 proposed PPPA requirements for ketoprofen 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). Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

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, the Commission proposes to amend 16 CFR part 1700 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 adding new paragraph (a)(25), reading as follows (although unchanged, the introductory text of paragraph (a) is republished below for context):

§ 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) Ketoprofen. Ketoprofen preparations for human use and containing more than 50 mg of ketoprofen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

* * * * *

Dated: November 15, 1996.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Proposed Rule to Require Child-Resistant Packaging for Ketoprofen,'' October 15, 1996.

2. Memorandum from Susan C. Aitken, Ph.D., HSHE, to Jacqueline Ferrante, Ph.D., HSPS, ''Toxicity of Ketoprofen,'' August 19, 1996.

3. 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 for OTC Pharmaceuticals Containing Ketoprofen,'' August 19, 1996.

4. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Proposed Rule to Require Child-Resistant Packaging for OTC Products Containing Ketoprofen,'' August 20, 1996.

5. Vale, J.S. and Meredith, T.J. Acute Poisoning Due to Non-steroidal Anti-inflammatory Drugs: Clinical Features and Management. Med. Toxicol. 1:12–31, 1986.

[FR Doc. 96–29691 Filed 11–19–96; 8:45 am]

BILLING CODE 6355–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232 and 240

[Release No. 34–37949; File No. S7–21–96]

RIN 3235–AG99

Lost Securityholders

AGENCY: Securities and Exchange Commission.

ACTION: Extension of the comment period.

SUMMARY: The Securities and Exchange Commission (''Commission'') is extending from October 28, 1996, until November 27, 1996, the comment period for Securities Exchange Act Release No. 37595 (August 22, 1996), 61 FR 44249 (August 28, 1996). In the release the Commission proposed two rules which are designed to address the problem of ''lost securityholders.''

DATES: Comments on the release should be submitted on or before November 27, 1996.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington DC 20549, and should refer to File No. S7–21–96. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. The file number should be included on the subject line if E-mail is used. Comment letters will be available for public inspection and copying at the Commission's public reference room, 450 Fifth St., NW, Washington DC 20549. Electronically submitted comment letters will be posted on the Commission's Internet Web site (http://www.sec.gov).

FOR FURTHER INFORMATION CONTACT: Jerry W. Carpenter, Assistant Director; Christine Sibille, Senior Counsel; or Michele Bianco, Attorney; at 202/942–4187, Office of Risk Management and Control, Mail Stop 5–1, Division of Market Regulation, Securities and Exchange Commission, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: On August 22, 1996, the Commission proposed two rules designed to address the problem of securityholders for whom a transfer agent or broker-dealer no longer has a current address. Rule 17Ad–17 would require transfer agents to conduct searches in an effort to locate lost securityholders. Rule 17a–24 would allow the Commission to gather data related to lost securityholders and to provide it to information distributors or others. The Commission also is seeking