owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of airplane controllability, or engine overspeed and consequent loss of engine power caused by the power levers being positioned below the flight idle stop while the airplane is in flight, accomplish the following:

(a) Within 30 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statements. This action may be accomplished by inserting a copy of this AD into the AFM.

''Positioning of power levers below the flight idle stop while the airplane is in flight is prohibited. Such positioning may lead to loss of airplane control or may result in an overspeed condition and consequent loss of engine power.''

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on June 12, 1997.

Issued in Renton, Washington, on May 19, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–13846 Filed 5–27–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–61–AD; Amendment 39–9995; AD 97–08–07]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–9–80 Series Airplanes and Model MD–88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in the above-captioned airworthiness directive (AD), which was published in the **Federal Register** on April 22, 1997 (62 FR 19477). The typographical error resulted in reference to an alert service bulletin that does not exist.

DATES: Effective May 7, 1997.

The incorporation by reference of certain publications listed in the regulations was previously approved by the Director of the Federal Register as of May 7, 1997 (62 FR 19477, April 22, 1997).

FOR FURTHER INFORMATION CONTACT: J. Kirk Baker, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5345; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: Airworthiness Directive (AD) 97–08–07, amendment 39–9995, applicable to certain McDonnell Douglas Model DC–9–80 series airplanes and Model MD–88 airplanes, was published in the **Federal Register** on April 22, 1997 (62 FR 19477). That AD supersedes an existing AD to continue to require an inspection to determine the type of fluorescent light ballasts installed in the cabin sidewall; and replacement, or removal/disconnection of the ballast, if necessary. That AD also continues to require, for some airplanes, removal of the dust barriers from the outboard ceiling panels, and installation of modified outboard ceiling panels. That AD also requires replacement of certain ballasts on which a protective cover is installed with other ballasts, or removal/disconnection of the ballast.

As published, AD 97–08–07 contained a typographical error, which appeared in paragraph (c)(1) of the AD. The error indicated that the actions required by that paragraph were to be accomplished in accordance with the Accomplishment Instructions of ''Boeing Alert Service Bulletin MD80–33A110.'' However, no such alert service bulletin exists. The correct alert service bulletin reference is ''McDonnell Douglas Alert Service Bulletin MD80–33A110.'' (In all other parts of the published AD and its preamble, the alert service bulletin was cited correctly.)

This document corrects the reference to the alert service bulletin cited in paragraph (c)(1) of AD–97–08–07, to read as follows:

* * * * *

''(1) Replace the Day-Ray Products Incorporated ballast and protective cover with a Bruce Industries Incorporated ballast, in accordance with Condition 2 of the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin MD80–33A110, dated February 25, 1997, or Revision 1, dated March 11, 1997. Or''

* * * * *

Since no other part of the regulatory information has been changed, the final rule is not being republished.

Issued in Renton, Washington on May 19, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–13845 Filed 5–27–97; 8:45 am]

BILLING CODE 4910–13–U

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

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

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing 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 determined that child-resistant packaging is necessary to protect children under five 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: The rule will become effective on November 24, 1997 and applies to

ketoprofen preparations packaged on or after that date.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Consumer Product Safety Commission, Washington, D.C. 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 five 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.[1, 2][1] For the past ten years, ketoprofen has been a prescription drug. Like most prescription drugs, it was required to be in CR 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 one tablet every four to six hours. The maximum daily dose is six tablets.[2]

3. Special Packaging

The current marketers are voluntarily placing ketoprofen in CR packaging. However, a mandatory special packaging standard for ketoprofen products will 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 five.[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 will also enable the Commission to ensure that its packaging meets the performance requirements of the PPPA test protocol set forth at 16 CFR 1700.15, 1700.20.

4. The Proposed Rule

On November 20, 1996, the Commission issued a notice of proposed rulemaking (''NPR'') that would require CR packaging for OTC drugs containing more than 50 mg of ketoprofen. 61 FR 59043. The Commission received only one comment, from the American Society of Health-System Pharmacists, in response to the proposed rule.[6] That comment expressed support for the proposed rule, stating that the toxicity data demonstrate that ketoprofen can cause serious illness and injury to children and that the proposed rule was consistent with packaging rules for other NSAIDs.

B. Toxicity of Ketoprofen

As explained in the NPR, 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, such as 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 ulcers with bleeding or perforation; intestinal ulcers; ulcerative stomatitis or colitis; gingival ulcers; 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 and ketoprofen overdoses.[2] The NPR provides details of some of these cases. 61 FR 59044–45.

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.

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). 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.[2]

The staff reviewed accidental ingestion data for children under age five. The American Association of Poison Control Center (''AAPCC'') collects incident data through its Toxic Exposure Surveillance System (''TESS''). Poisoning incidents involving ketoprofen from 1985 to 1994 were not recorded separately from other NSAIDs unless they were fatal. No deaths involving ketoprofen were reported during this period.[2] In 1995, CPSC

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

staff requested a separate report on ketoprofen. This report showed 250 accidental ingestions of ketoprofen involving children under five years old in 1995. Twelve of these incidents resulted in minor outcomes.[8]

CPSC's data base, the National Electronic Injury Surveillance System (''NEISS'') monitors emergency room visits to selected hospitals throughout the United States. As stated in the NPR, review of NEISS data from 1988 to June 1996 showed three cases involving ketoprofen and children under five years old. All three incidents occurred in 1996. None were fatal or required hospitalization.[2] Since publication of the NPR, seven new cases of children ingesting ketoprofen were reported through NEISS.[8]

C. Level for Regulation

This rule requires special packaging for OTC ketoprofen products containing more than 50 mg ketoprofen per retail package, the same level as proposed in the NPR. This level is based on established guidelines for medical treatment following pediatric ingestion of NSAIDs.[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 and in the NPR, 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 concludes that a regulation is needed to ensure that products subject to the regulation will be placed in CR packaging. 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 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 it will adequately protect the integrity of the substance and not interfere with the substance's intended storage or use.[4, 10]

The current marketers of OTC ketoprofen voluntarily use CR packaging. 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, 4, 10]

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 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 quantities of ketoprofen will be marketed in non-CR packaging before a 180-day effective date, other than in 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. Accordingly, this rule will take effect 180 days after its publication in the **Federal Register** and will 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.

When the Commission issued its proposed rule, 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.[3] 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 ketoprofen are using CR packaging and the relatively low costs of CR packaging should not be an entry burden for future marketers. The Commission received no comments on this determination and is aware of no information that would alter its determination.[9] Therefore, the Commission certifies that this rule would not have a significant impact on a substantial number of small businesses or other small entities.

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 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, as stated in the proposed rule, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.[3]

H. Preemption

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, ''no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard.'' 15 U.S.C. 1476(a). A State or local standard may be excepted from this preemptive effect if (1) the State or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the State or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through a process specified at 16 CFR Part 1061. 15 U.S.C. 1476(c)(1). Also, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the rule requiring CR packaging for ketoprofen would preempt non-identical state or local special packaging standards for ketoprofen.

I. Other Executive Orders

The Commission certifies that the rule does not have sufficient implications for federalism to warrant a Federalism Assessment under Executive Order 12612 (October 26, 1987). Independent regulatory agencies are encouraged, but not required, to comply with Executive Order 13045 (April 23, 1997). This rulemaking is not subject to that order because it is not a ''covered agency action'' as defined in the order and because the rulemaking was initiated before the order was issued. In any event, the Commission's discussion in this notice of the issues involved in the rulemaking comply with the order's requirements for an analysis of the rule and its environmental, health and safety effects on children.

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)(26) 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:

* * * * *

(26) *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: May 21, 1997.

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. 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, EC, 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.
6. Letter from Gary C. Stein, Ph.D., Senior Government Affairs Associate, American Society of Health-System Pharmacists, to Office of the Secretary, CPSC, dated January 30, 1997.
7. Briefing memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Final Rule to Require Child-Resistant Packaging for Ketoprofen,'' May 5, 1997.
8. Memorandum from Susan C. Aitken, Ph.D., HSHE, to Jacqueline Ferrante, Ph.D., HSPS, ''Update of Injuries to Accidental Ingestion of Ketoprofen Products,'' March 4, 1997.
9. Memorandum from Marcia P. Robins, EC, to Jacqueline Ferrante, Ph.D., HSPS, ''Final Rule for Child-Resistant Packaging for OTC Packages Containing More than 50 mgs Ketoprofen: Regulatory Flexibility Issues,'' February 18, 1997.
10. 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 Products Containing Ketoprofen,'' February 27, 1997.

[FR Doc. 97–13842 Filed 5–27–97; 8:45 am]

BILLING CODE 6355–01–P

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Final rule.

SUMMARY: This rule amends existing regulations governing requests for waiver of the two-year home-country physical presence requirement made by interested United States Government agencies on behalf of an exchange visitor. Changes to the regulations governing waiver requests by interested United States Government agencies are