CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Final Rule: Requirements for Child-Resistant Packaging; Household Products With More Than 50 mg of Elemental Fluoride and More Than 0.5 Percent Elemental Fluoride; and Modification of Exemption for Oral Prescription Drugs with Sodium Fluoride

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a rule to require child-resistant (''CR'') packaging for household products containing more than the equivalent of 50 mg of elemental fluoride *and* more than the equivalent of 0.5 percent elemental fluoride (on a weight-to-volume (''w/v'') or weight-to-weight (''w/w'') basis). For consistency, the Commission is also modifying the oral prescription drug exemption for sodium fluoride preparations. Instead of exempting drugs with no more than 264 mg of sodium fluoride per package as the current rule does, the Commission will exempt such drugs with either 50 mg or less of the equivalent of elemental fluoride (110 mg or less of sodium fluoride) per package or no more than the equivalent of 0.5 percent elemental fluoride on a w/v or w/w basis. The Commission determines that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from handling or ingesting a toxic amount of elemental fluoride. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: The rule will become effective on March 2, 1999, and applies to products packaged on or after that date.

FOR FURTHER INFORMATION CONTACT: Laura Washburn, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0400 ext. 1452.

SUPPLEMENTARY INFORMATION:

A. Background

1. Household Products Containing Fluoride

Fluorides are ingredients in such household products as cleaning solutions for metal, tile, brick, cement, wheels, radiators, siding, toilets, ovens and drains. Fluorides are also found in rust and water stain removers, silver solder and other welding fluxes, etching compounds, laundry sour, air conditioner coil cleaners and floor polishes. The fluorides that may be ingredients in these products and are potentially toxic are hydrofluoric acid (''HF''), ammonium bifluoride, ammonium fluoride, potassium bifluoride, sodium bifluoride, sodium fluoride and sodium fluosilicate.[1][1&3] [2]

Many dental products also contain fluorides, but at lower levels. In general, the concentrations of elemental fluoride in household cleaners and surface preparation agents are 10 to 1,000-fold higher than concentrations found in dental products.[2]

2. 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 (1) 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) 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.

3. Existing PPPA Requirements for Fluoride-Containing Products

The Commission currently requires CR packaging for oral prescription drugs with fluoride, but it exempts those in liquid or tablet form that contain no more than 264 mg of sodium fluoride (equivalent to 120 mg fluoride) per package. 16 CFR 1700.14(10)(vii). The Commission based this exemption level on the lack of serious adverse human experience associated with such drugs at that time and a recommendation by the American Dental Association that no more than 264 mg of sodium fluoride should be dispensed at one time. 45 FR 78630. As discussed below, the Commission is revising the exemption to a new level that is based on current information concerning the toxicity of fluoride and is consistent with the CR requirement for fluoride-containing household products.

4. The Proposed Rule

On November 20, 1997, the Commission issued a notice of proposed rulemaking (''NPR'') that would require CR packaging for household products containing more than the equivalent of 50 mg of elemental fluoride and more than the equivalent of 0.5 percent elemental fluoride (w/v or w/w). The Commission also proposed to adjust the oral prescription drug exemption so that it would be consistent. 62 FR 61928. The Commission received four comments in response to the proposed rule.

One commenter noted that the language of the revised exemption needed to be clarified. The Commission intended that products satisfying either one of the criteria specified would qualify for the exemption. Accordingly, the Commission has clarified the final rule so that it exempts sodium fluoride drug preparations that contain no more than 50 mg of the equivalent of elemental fluoride (110 mg or less of sodium fluoride) per package *or* no more than the equivalent of 0.5 percent elemental fluoride on a w/w or w/v basis.

The Commission received a letter from the American Dental Association stating that it does not object to the proposed rule. The third comment came from the Art and Creative Materials Institute, a non-profit association of manufacturers of art and creative materials, expressing support for the

[1] The percentage of elemental fluoride in any compound is determined by dividing the molecular weight of fluoride (~619 grams/mole) by the molecular weight of the compound (e.g., the molecular weight of sodium fluoride = 42 grams/mole). Sodium fluoride contains 45% elemental fluoride ($^{19}/_{42} \times 100 = 45\%$).

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

proposed rule. The Chemical Manufacturers Association also commented in support of the proposed rule.

B. Toxicity of Fluoride

Most available toxicity information on fluoride relates to acute toxicity of hydrofluoric acid (''HF''). However, other water soluble fluoride-containing compounds can cause fluoride poisoning. The fluoride ion is systemically absorbed almost immediately. It is highly penetrating and reactive and can cause both systemic poisoning and tissue destruction. Fluoride ions, once separated from either HF or fluoride salts, penetrate deep into tissues, causing burning at sites deeper than the original exposure site. The process of tissue destruction can continue for days.[2]

Fluoride absorption can produce hyperkalemia (elevated serum potassium), hypocalcemia (lowered serum calcium), hypomagnesemia (lowered serum magnesium), and metabolic and respiratory acidosis. These disturbances can then bring on cardiac arrhythmia, respiratory stimulation followed by respiratory depression, muscle spasms, convulsions, central nervous system (''CNS'') depression, possible respiratory paralysis or cardiac failure, and death. Fluoride may also inhibit cellular respiration and glycolysis, alter membrane permeability and excitability, and cause neurotoxic and adverse GI effects.[2]

When exposure is through inhalation, fluorides can cause severe chemical burns to the respiratory system. Inhalation can result in difficulty breathing (dyspnea), bronchospasms, chemical pneumonitis, pulmonary edema, airway obstruction, and tracheobronchitis. The severity of burns from dermal absorption can vary depending on the concentration of fluoride available, duration of the exposure, the surface area exposed, and the penetrability of the exposed tissue. Ocular exposure can result in serious eye injury.[2]

Ingestion of fluoride can result in mild to severe GI symptoms. Reports suggest that ingesting 3 to 5 milligrams of fluoride per kilogram of body weight (mg/kg) causes vomiting, diarrhea, and abdominal pain. Ingestion of more than 5 mg/kg may produce systemic toxicity. A retrospective poison control center study of fluoride ingestions reported that symptoms, primarily safely tolerated GI symptoms that tended to resolve within 24 hours, developed following ingestions of 4 to 8.4 mg/kg of fluoride.[2] According to the medical literature, a safely tolerated dose (''STD'') and a certainly lethal dose (''CLD'') were determined from 600 fluoride poisoning deaths. The CLD was determined to be 32 to 64 mg/kg and the STD was estimated at one fourth that, or 8 to 16 mg/kg. These values were statistically determined and are not identical to the actual lowest toxic or lethal levels of fluoride. The lowest documented lethal dose for fluoride is 16 mg/kg in a 3-year-old child. There were complicating factors in this death. The child may have taken other medications and he suffered from Crohn's disease (an inflammatory disorder of the GI tract) that may have contributed to his death.[2]

C. Injury Data

Medical Literature. There are many reports in the medical literature of deaths and injuries involving fluoride-containing products. A retrospective study conducted by the American Association of Poison Control Centers (''AAPCC'') of hydrofluoric acid burns from rust stain removers applied to clothing found 619 such cases in 1990. Five of these required hospitalization.[2] Other reports gathered from the medical literature are discussed in the notice of proposed rulemaking and the accompanying briefing package. 62 FR 61928.

CPSC Databases. CPSC has several databases for poison incidents. The staff reviewed cases from 1988 to May 1997 in the National Electronic Injury Surveillance System (''NEISS''), the Injury or Potential Injury Incident files, Death Certificate (''DCRT'') database, and In-Depth-Investigation (''INDP'') files.

From 1988 to 1996, NEISS had reports of 31 incidents involving products documented to contain fluoride. Two of these were accidental ingestions by children under 5 years old. Most other injuries involved chemical burns of the hands.[2] In addition, 1997 NEISS reports show six adults experienced burns while using fluoride-containing products. In 1997, NEISS had reports of an additional five cases involving children under 5 years old ingesting products containing fluoride. For 1997, NEISS also reported an additional three cases of children under 5 years old involving products that might have contained fluoride.[7]

The INDP files contain numerous injury reports. For example, a 50-year-old woman was using a water stain remover with 6 percent HF when it leaked through her rubber gloves and to her skin. She developed intense pain 4 hours later when the fluoride ion penetrated through to the bones of her forearm. Four months after the incident she had only partial use of her arm and hand. Three reports in the INDP files involve children under 5 years old who died after ingesting fluoride-containing products. A 3-year old child ingested an unknown product with HF. The second case involved a 2-year-old child who ingested a toilet bowl stain remover that contained 15.9 percent ammonium bifluoride. The most recent case was an 18-month-old child who ingested an unknown amount of air conditioner coil cleaner with 8 percent HF and 8 percent phosphoric acid.[2]

Since 1995, there were six reports of fluoride poisoning in children under 5 years of age from a wheel cleaning product. The product contains ammonium bifluoride and ammonium fluoride salts, reportedly containing at least 15 percent fluoride. Before December, 1996, it was marketed for household use in non-CR packaging. Since that date it has been packaged in CR packaging, and in September 1997 it was recalled by the manufacturer.[2]

Three deaths from fluoride-containing products were documented in 1997 after the staff had completed the briefing package for the proposed rule. Two involved children under 5 years old. In one case, a 3-year-old female died from cardiac arrest after ingesting the recalled wheel cleaner described above. The second death involved a 19-month-old female who ingested a rust remover with hydrofluoric acid and ammonium bifluoride. Finally, a 38-year-old male died from cardiac arrest after unintentional ingestion of a rust remover with ammonium bifluoride.[6]

AAPCC Data. The staff reviewed AAPCC ingestion data involving children under 5 years old and products known to, or that may, contain fluoride. (The actual number of fluoride exposures cannot be determined because some products that contain fluoride are not identified as such and therefore may be coded to generic categories such as acidic cleaning products or other unknown cleaning products.) From 1993 to 1995, there were no reported fatalities in this age group. Out of a total of 499 exposures to products known to contain HF, there were 2 major [3] outcomes and 24 moderate [4] outcomes. The AAPCC data

[3] Major outcome—The patient exhibited signs or symptoms which were life-threatening or resulted in significant residual disability or disfigurement.

[4] Moderate outcome—The patient exhibited signs and symptoms that were more pronounced, more prolonged, or more of a systemic nature. Usually some form of treatment was required. Symptoms were not life-threatening and the patient had no residual disability or disfigurement.

also show 23 major outcomes and 188 moderate outcomes for other acid household products. Some of these may have contained fluoride. The frequency of injury for dental treatments was much lower than that for household products containing HF. Of approximately 23,000 exposures to such dental products, there were 34 moderate outcomes, and the only documented major outcome was a miscoded incident where the child experienced an allergic reaction to the product rather than systemic toxicity from an overdose.[2]

The 1996 AAPCC data report 136 exposures to products known to contain HF involving children under 5 years old. Four of these resulted in moderate outcomes. There were no major outcomes or deaths reported with this age group in 1996.[7]

The staff also compiled data from AAPCC annual reports for all ages and all routes of exposure for the years 1985 to 1995. During this time period, there were about 25,000 exposures to products containing HF. Of these, 2,881 resulted in moderate outcomes and 275 in major outcomes. There were also injuries from dental products, fluoride mineral/electrolyte products, and vitamins with fluoride. A total of 18 deaths were reported in the HF category. Two deaths involved children under 5 years old. One ingested an ammonium bifluoride toilet stain remover (described above) and the other child died after ingesting a toilet cleaner with HF. Generally, these AAPCC data suggest that household products with HF pose a more serious risk of injury than other classes of fluoride products. Moderate to serious outcomes developed in 12.8 percent of the exposures to HF compared to only 0.4 percent of the exposures to anticaries products.[2]

The 1996 AAPCC data for all ages and all routes of exposure show that for 1996 there were about 2944 exposures to products containing HF. Of these, 742 resulted in moderate outcomes and 27 in major outcomes. Four deaths were reported involving HF.[7]

D. Level of Regulation for Household Products Containing Fluoride

The Commission is issuing a rule that requires special packaging for household products containing more than the equivalent of 50 mg of elemental fluoride and more than the equivalent of 0.5 percent elemental fluoride on a w/v basis for liquids or a w/w basis for non-liquids.[1,2&5] This is the same level as the Commission proposed.

There is no well defined lethal dose for fluoride. In the medical literature, one source cites a minimum lethal dose in humans of 71 mg/kg and another specifies a lethal oral dose in the range of 70 to 140 mg/kg. The staff considers these values too high based on documented cases of fluoride toxicity. There is one documented death from ingestion of 16 mg/kg fluoride, but as discussed above, other medical factors may have contributed to that death. Most evidence suggests that the lower limit of the calculated CLD of 32 mg/kg is a reasonable estimate for a minimum lethal dose.[2]

Similarly, there is no established toxic dose for fluoride. Generally, greater than 6 percent HF can cause dermal burns and more than 0.5 percent can lead to serious eye injury. Several reports suggest ingestion of 3 to 5 mg/kg produces symptoms and that more than 5 mg/kg (50 mg in a 10 kg child) can produce systemic toxicity. Additionally, some medical professionals advise medical observation following ingestions of more than 5 to 8 mg/kg. Based on this information, the Commission determined a level for regulation that would include all household products with more than 50 mg of elemental fluoride and more than 0.5 percent elemental fluoride on a w/v basis for liquids or a w/w basis for non-liquids. There is no evidence that 50 mg or less of elemental fluoride or concentrations less than 0.5 percent cause serious systemic toxicity or serious burns.[1,2&5]

E. Level of Regulation for Oral Prescription Drugs Containing Sodium Fluoride

Based on the toxicity information discussed above, the Commission believes that the current exemption for oral prescription drugs with no more than 264 mg of sodium fluoride should be modified. To be consistent with the level for household products containing fluoride, the Commission is revising the level for the oral prescription drug exemption to exempt products that have either no more than the equivalent of 50 mg of elemental fluoride (110 mg sodium fluoride) per package or no more than a concentration of 0.5 percent elemental fluoride on a w/v basis for liquids or a w/w basis for non-liquids.[1,2&5]

The Commission does not believe that changing the level of exemption for prescription drugs containing sodium fluoride will impact any of the currently exempted dental products with more than 50 mg of fluoride because these products have 0.5 percent or less fluoride.[1] In its comment, the American Dental Association confirmed this.[5]

F. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning children's ingestion of fluoride demonstrate that fluoride can cause serious illness and injury to children. Moreover, it is available to children in common household products. Although some products currently use CR packaging, others do not. The Commission concludes that a regulation is needed to ensure that products subject to the regulation will be placed in CR packaging by any current as well as future manufacturers.[1,2&5]

The same hazard posed to children by toxic amounts of fluoride in household products also exists from such levels of fluoride in oral prescription drugs. Therefore, the Commission is modifying the existing exemption for such drugs with sodium fluoride to reflect current toxicity data and be consistent with the level for fluoride-containing household products.[1&2]

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 handling or ingesting fluoride 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 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.[4,9]

Some OTC fluoride-containing household products are packaged in containers with non-CR continuous threaded closures. The Commission also is aware of such products packaged in aerosols and mechanical pumps. Various types and designs of senior friendly CR packaging can be readily obtained that would be suitable for fluoride-containing products.[3&4]

Two manufacturers currently use senior-friendly continuous threaded CR packaging for their fluoride-containing household products. Another manufacturer uses a senior-friendly trigger mechanical pump mechanism for its product. This shows that these types of CR packages are technically feasible, practicable and appropriate for fluoride-containing products. The Commission knows of at least one fluoride product that uses a non-CR aerosol package. The manufacturer of another regulated product is currently using a senior-friendly CR aerosol overcap. Thus, this kind of CR packaging could be used for fluoride-containing products. Finally, various designs of senior-friendly snap type reclosable CR packaging that would be appropriate for non-liquid fluoride-containing products are available. Thus, appropriate senior-friendly CR packaging is available for products marketed in continuous threaded, snap, aerosols, and trigger spray packaging.[4] Therefore, the Commission concludes that CR packaging for fluoride-containing products 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 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.

G. 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.

Senior-friendly special packaging is currently commercially available for most types of CR packaging.[9] Therefore, the Commission believes that an effective date of 9 months after publication of the final rule is reasonable. The Commission proposed a 9 month effective date and received no comments on this issue. If companies do find that they need more time, they can request a stay of enforcement for the minimum period needed to obtain adequate supplies of senior-friendly CR packaging.

A final rule would apply to products that are packaged on or after the effective date.

H. 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.

In connection with the proposed rule, the Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to require special packaging for household products containing fluoride with more than 50 mg elemental fluoride and more than 0.5 percent elemental fluoride (w/v or w/w). The staff also considered the impact of a rule modifying the current exemption for oral prescription drugs containing sodium fluoride so that it would be consistent with the level proposed for household products.[3]

Based on this assessment, the Commission concluded that the proposed requirement for fluoride-containing household products would not have a significant impact on a substantial number of small businesses or other small entities. Despite making a specific request in the NPR, the Commission received no comments concerning the potential impact on small businesses, and the Commission is unaware of any information that would alter its conclusion that the rule will not have a significant impact on a substantial number of small entities.[8]

The Commission reached the same conclusion concerning the proposed modification in the level for exemption of oral prescription drugs containing sodium fluoride.[3] No additional information was provided to alter the Commission's conclusion that the modification to the exemption for oral prescription drugs containing sodium fluoride would not have a significant impact on a substantial number of small businesses or other small entities.[8]

I. Environmental Considerations

Also in connection with the proposed rule and pursuant to the National Environmental Policy Act, 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 fluoride-containing products.[3] The Commission concluded that the proposed rule would have no adverse effect on the environment, and neither an environmental assessment nor an environmental impact statement would be required. No additional information alters this conclusion.[8]

J. Executive Orders

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). In addition, 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 household products containing fluoride above the regulated level and modifying the exemption level for oral prescription drugs with sodium fluoride would preempt non-identical state or local special packaging standards for such fluoride containing products.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the rule does

not have sufficient implications for federalism to warrant a Federalism Assessment.

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 amends 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

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

Authority: 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 to revise paragraph (a)(10)(vii) and to add paragraph (a)(27) to read as follows (the introductory text of paragraphs (a) and (10) are republished without change 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 meeting the requirements of § 1700.20(a) 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:

* * * * *

(10) *Prescription drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription or a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

* * * * *

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package or not more than a concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to this § 1700.14(a)(10).

* * * * *

(27) *Fluoride.* Household substances containing more than the equivalent of 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of § 1700.15(a), (b) and (c).

* * * * *

Dated: May 27, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Jacqueline Ferrante, Ph.D., EH, to the Commission, ''Proposed Rule to Require Child-Resistant Packaging for Household Products with Fluoride,'' September 30, 1997.

2. Memorandum from Susan C. Aitken, Ph.D., EH, to Jacqueline Ferrante, Ph.D., EH, ''Toxicity of Household Products Containing Fluoride,'' August 4, 1997.

3. Memorandum from Marcia P. Robins, EC, to Jacqueline Ferrante, Ph.D., EH, ''Market Data, Economic Considerations and Environmental Effects of a Proposal to Require Child-Resistant Packaging for Household Products Containing Fluoride,'' June 20, 1997.

4. Memorandum from Charles Wilbur, EH, to Jacqueline Ferrante, Ph.D., EH, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Proposed Rule to Require Child-Resistant Packaging for OTC Products Containing Fluoride,'' June 27, 1997.

5. Briefing memorandum from Jacqueline Ferrante, Ph.D., EH, to the Commission, ''Final Rule to Require Child-Resistant Packaging for Household Products with Fluoride,'' May 6, 1998.

6. Memorandum from Susan C. Aitken, Ph.D., EH, to Jacqueline Ferrante, Ph.D., EH, ''Update on Injuries Due to Products Containing Fluoride,'' October 9, 1997.

7. Memorandum from Susan C. Aitken, Ph.D., EH, to Jacqueline Ferrante, Ph.D., EH, ''Injuries Due to Products Containing Fluoride,'' April 20, 1998.

8. Memorandum from Marcia P. Robins, EC, to Jacqueline Ferrante, Ph.D., EH, ''Final Rule: Child-Resistant Packaging for Household Products Containing Fluorides,'' April 8, 1998.

9. Memorandum from Charles Wilbur, EH, to Jacqueline Ferrante, Ph.D., EH, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Special Packaging for Products Containing Fluoride,'' March 10, 1998.

[FR Doc. 98–14449 Filed 6–1–98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 10

[T. D. 98–52]

RIN 1515–AC18

Procedural Change Regarding American Shooks and Staves

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by requiring the submission of a Customs Form (CF) 4455, Certificate of Registration, rather than a CF 3311, Declaration for Free Entry of Returned American Products, when shooks and staves produced in the United States are exported from the United States with the intention that they will be returned to the United States, exempt from duty, in the form of complete boxes or barrels in use as usual containers of merchandise. When boxes or barrels made from the exported American shooks and staves, for which a CF 4455 has been submitted, are imported, the importer of the boxes or barrels must use the CF 4455 as well to make such a claim. Shooks and staves produced in the United States that are exported and so returned are exempt from customs duties provided their identity is established by the proper submission of the CF 4455. The amendment helps to clarify the procedures regarding the free entry of such American produced shooks and staves returned to the United States.

EFFECTIVE DATE: July 2, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas Wygant, Office of Field Operations, 202–927–1167.

SUPPLEMENTARY INFORMATION:

Background

Section 10.5, Customs Regulations (19 CFR 10.5) provides that shooks and staves produced in the United States and returned in the form of complete boxes or barrels in use as the usual containers of merchandise are exempt from any duties imposed by the tariff laws upon similar containers made of foreign shooks or staves, provided their identity is established under the regulations.

Paragraph (d) of § 10.5 provides that an exporter of shooks or staves in respect of which free entry is to be claimed when returned as boxes or barrels shall file a notice of intent to export on a Customs Form (CF) 3311 in triplicate with the director of the port of