United States

CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

VOTE SHEET

DATE : MAY 6 1998

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey Bromme, General Counsel
Stephen Lemberg, Assistant General Counsel
Patricia M. Pollitzer, Attorney, OGC

SUBJECT : Final PPPA Rule Requiring Child-Resistant Packaging for Household Products with Fluoride and Modifying Prescription Drug Exemption for Sodium Fluoride

Attached is a staff briefing package recommending that the Commission issue a final rule requiring child-resistant packaging under the Poison Prevention Packaging Act for household products containing the equivalent of more than 50 mg of elemental fluoride and more than the equivalent of 0.5 percent elemental fluoride. The staff also recommends that the Commission modify the current exemption for oral prescription drugs with sodium fluoride so that the exemption level would be consistent with the recommended level for household products. Tab G of the package contains a draft Federal Register notice that reflects both of the staff's recommendations.

Please indicate your vote on the following options.

I. Approve the Federal Resister notice as drafted.

(Signature) (Date)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial _____ Date 5/6/98

CPSA 6 (b)(1) Cleared
5/6/98
No Mfrs/PrvtLblrs or Products Identified

II. Approve the draft Federal Register notice with the following changes (please specify).

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not approve the draft Federal Register notice.

_____ _____

(Signature) (Date)

IV. Take other action (please specify).

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment

Briefing Package

Final Rule to Require Child-Resistant Packaging for Household Products with Fluoride

For Information Contact:
Jacqueline Ferrante, Ph.D.
Directorate for Epidemiology & Health Sciences
(301) 504-0477

NOTE: This document has not been reviewed or accepted by the Commission.
Initial mlc **Date** 5/6/98

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No Mfrs/PrvtLblrs
Products Identified
Excepted

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Executive Summary

On November 20, 1997, the Commission proposed a special packaging standard for household products with more than the equivalent of 50 mg of elemental fluoride and more than the equivalent of 0.5 percent elemental fluoride. The Commission also proposed to modify the exemption for oral prescription drugs with fluoride so that the exemption would be consistent with the proposed rule. The staff received four comments. None opposed the proposed rule or the proposed modification.

Fluoride can cause severe penetrating bums and systemic effects. Deaths and serious injuries have resulted from toxic exposure to fluoride in both children and adults. Three deaths were reported within the last year, two involved children under five years old. The types of products that would be subject to a special packaging standard are those with high concentrations of fluoride in the form of hydrofluoric acid or soluble, inorganic salts, including various cleaners (e.g., metal, toilet, etc.), rust removers, and etching creams. Dental products would **not** be included because the concentration of elemental fluoride in currently marketed products is 0.5 percent or less.

Special packaging is technically feasible, practicable., and appropriate for household products with fluoride. Some companies voluntarily use child-resistant packaging (CRP). A special packaging requirement for fluoride-containing products is not expected to have a significant impact on a substantial number of small businesses or have environmental effects. Senior-friendly CRP is readily available at competitive prices with non-CRP. No comments were received from small businesses and no additional information was provided concerning glass etching creams.

The staff recommends that the Commission issue a special packaging standard for all household products with 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) basis for liquids or a weight-to-weight (w/w) basis for nonliquids. The staff also recommends modifying the level for exemption for oral prescription drugs with sodium fluoride, to that for special packaging of other products with fluoride.

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MAY 6 1998

To: The Commissibn
Sadye E. Dunn, Secretary

Through: Jeffrey S. Bromme, General Counsel
Through: Pamela Gilbert, Executive Director

From: Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction RLM
Jacqueline N. Ferrante, Ph.D., Pharmacologist, Directorate for Epidemiology/ and Health Sciences, Division of Health Sciences

Subject: Special Packaging Standard for Household Products with Fluoride

Background

On November 20, 1997, the Commission proposed a special packaging standard for household products with fluoride because these products may cause serious harm and death in young children (Tab A). Additionally, the Commission proposed to modify the exemption for oral prescription drugs with fluoride to be consistent with the proposed special packaging standard. Detailed information concerning this issue was provided to the Commission in a briefing package dated September 30, 1997.

The acute toxicity of fluoride is well established. Hydrofluoric acid and fluoride salts found in products such as metal/toilet cleaners, rust removers, and etching creams, can dissociate fluoride ions (F^-) leading to penetrating tissue destruction and systemic poisoning. Deaths and serious injuries have been reported in children and adults following exposure to fluoride-containing products. The staff determined that products with **both** more than 50 milligrams (mg) and 0.5 percent elemental fluoride could potentially cause serious toxicity. Products that contain more than 50 mg per package, but have a concentration of 0.5 percent or less would not be subject to a special packaging standard. Dental products would be included in this category. This is consistent with the lack of injury data for both over-the-counter (OTC) and exempted prescription (Rx) fluoride-containing dental products. The following table clarifies which fluoride-containing products would be subject to a special packaging standard.

CPSA 6 (b)(1) Cleared
5/6/98
No Mfrs/PrvtLblrs or
Products Identified
Excepted

NOTE: This document has not been reviewed or accepted by th Commission.
Initial Date 5/6/98

Fluoride-Containing Products **Subject** to a **Special Packaging** Standard

Product contains > 50 mg elemental fluoride	Product contains > 0.5% elemental fluoride	Subject to a special packaging standard
Yes	Yes	Yes
No	Yes	No
Yes	No	No
No	No	No

Public Comments

The Commission received four comments in response to the proposed rule (Tab B). Colgate Oral Pharmaceuticals requested clarification regarding the exemption. The FR notice stated that the proposed exemption applies to sodium fluoride drug preparations that contain 50 mg or less of the equivalent of elemental fluoride (110 mg or less of sodium fluoride) per package **and** no more than the equivalent of 0.5 percent elemental fluoride on a weight to weight (w/w) or weight to volume (w/v) basis. The staff intended that products satisfying only one of these criteria would qualify for an exemption. Therefore, the wording for the exemption should be modified to exempt those sodium fluoride drug preparations that contain 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/w or w/v basis.

The Chemical Manufacturers Association supports the proposed rule and the American Dental Association (ADA) had no objection to it. The ADA agrees that currently marketed OTC and Rx dental products with fluoride intended for home use have not been shown to pose a significant hazard to young children. Additionally, the ADA stated that "there are no currently marketed dental products that meet both of the proposed criteria for child-resistant packaging."

The Commission specifically requested information on the uses and marketing patterns of glass etching creams. No information was received related to this issue except that the Art and Creative Materials Institute, an international association of manufacturers of art and creative materials (including glass etching creams), support the proposed rule.

The staff sent letters to 65 companies that market or may market fluoride-containing products informing them of the proposed rule and requesting comments. Only two companies responded and neither markets fluoride-containing products. Five letters were returned with no forwarding address.

Updated Injury Data

The staff updated injury data from fluoride-containing products since publication of the proposed rule (Tab A) which contained injury data from the medical literature, CPSC databases, and the American Association of Poison Control Centers (AAPCC). There were three additional deaths documented, two involved children under five years old (Tab C). These were not in the briefing package for the proposed rule, but were discussed at the public briefing in October 1997. In one case a 3-year-old female ingested a wheel cleaner that contained ammonium fluoride and ammonium bifluoride salts. She vomited, her blood pressure dropped, and she became cyanotic. She died following cardiac arrest. The second death involved a 19-month-old female who ingested a rust remover with hydrofluoric acid and ammonium bifluoride. The third incident involved a 38-year-old male who unintentionally ingested one-half cup of rust remover with ammonium bifluoride. He died four hours post-ingestion from cardiac arrest. In another incident, an 18-month-old child ingested an unknown amount of rust remover. This child was examined in a hospital, but released the next day without any injuries.

From June 1, 1997 to February 28, 1998, there were a number of injuries from fluoride-containing products reported in the National Electronic Injury Surveillance System (NEISS) database (Tab D). Six involved adults who experienced bums to the fingers, hands, or arms after using hydrofluoric acid (HF) cleaners. In another case, an 18-year-old female had chemical bums on her back and abdomen after she used a rust remover on a shirt, washed the shirt, and wore it.

Five other NEISS cases reported during this period involved children under five years old. Three involved rust removers with HF. A 12-month-old male spilled some rust remover on his right leg causing bums and he also may have ingested some of the product. A 12-month-old female was discovered pouring rust remover into a cup. Although the child had a blistered lip, the parents did not think the child ingested the product. In another case, a 2-year-old male ingested an unknown quantity of rust remover. All three of these children were treated and released. The other two NEISS cases involved a wheel cleaning product with ammonium fluoride salts. In one case a 2-year-old male sprayed the cleaner in his mouth. This child was treated and released. In the second case, a 21 -month-old male was hospitalized after an accidental ingestion of this product. This incident is still under investigation.

The staff also reviewed data from the AAPCC for 1996 (Tab C). No fatalities or major' injuries occurred in children under five years old exposed to HF products. One major injury was documented in a child following the ingestion of an electrolyte/mineral fluoride preparation. AAPCC data for all ages and all routes of exposure showed that moderate* to major outcomes developed in 14.2 percent of exposures to household products with HF compared to 0.5 percent of exposures to anti-caries products with fluoride. This is consistent with the lower concentration 'of fluoride in the anti-caries product category.

The draft Federal Register notice (Tab G, pp. 7 - 11) summarizes all of the injury data (incidents discussed in the notice of proposed rulemaking as well as the updated information).

Regulatory Flexibility and Environmental Issues

The staff concludes that a special packaging requirement for fluoride-containing products will not have a significant impact on a substantial number of small businesses (Tab E). Senior-friendly CRP is readily available at competitive prices with non-CRP. Some manufacturers of fluoride-containing products are voluntarily using senior-friendly CRP. The proposal will have no significant effects on the environment because the manufacture, use, and disposal of CR and non-CRP is virtually the same.

Technical Feasibility, Practicability, and Appropriateness

Available data support a conclusion that special packaging for fluoride-containing products is technically feasible (producible), practicable (lends itself to mass production techniques), and appropriate (compatible with the product) (Tab F). Senior-friendly CRP is available for products marketed in continuous threaded, snap, aerosols, and trigger spray packaging. Senior-friendly continuous threaded CRP is currently used by two manufacturers and another manufacturer uses a senior-friendly trigger mechanical pump mechanism for its product.

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 regulation is issued, unless the Commission determines that an earlier effective date is in the public interest. The Commission proposed that a final rule would take effect nine months after publication of the final rule since senior-friendly special packaging is commercially available for most types of CRP. Full commercial availability for senior-friendly mechanical pump packages and aerosol overcap packages could take from nine

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'Major outcome - The patient exhibited signs or symptoms which were life-threatening or resulted in significant residual disability or disfigurement

*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 is required. Symptoms were not life-threatening and the patient had no residual disability or disfigurement.

months to one year. The Commission proposed a nine month effective date and did not receive any comments related to this issue. Therefore, the staff concludes that an effective date of nine months after publication of the final rule is reasonable for most fluoride-containing products. As stated in the draft Federal Register notice, companies needing more time can request a stay of enforcement for the minimum period needed to provide adequate supplies of senior-friendly CRP.

Options

1. The Commission may issue a rule requiring special packaging for household products with 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) if the Commission preliminarily finds that:

   i) special packaging is required to protect young children from serious personal injury or illness from handling, using, or ingesting the product; and

   ii) special packaging is technically feasible, practicable, and appropriate.

2. The Commission may also issue a rule to amend the level for exemption for oral prescription drugs with sodium fluoride to be consistent with that for other products with fluoride.

3. The Commission may decline to issue either or both of these rules if it is unable to make the necessary findings.

Recommendation

The toxicity of fluoride is well established and exposure to fluoride-containing products has resulted in serious injuries and deaths. The staff recommends that the Commission issue a special packaging standard for all household products with 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 nonliquids. To maintain consistency within the PPPA regulations, the staff also recommends amending the level for exemption for oral prescription drugs with sodium fluoride. A draft final rule is at Tab G.

TAB A

SIAP, GPS RWY 25 SIAP, and GPS RWY 29 SIAP and other IFR operations at Tracy Municipal Airport. Tracy. CA. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.E dated September 10.1997, and effective September 16.1997, 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 invovles 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 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 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 7 1 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.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E. Airspace Designations and Reporting Points, dated September 10.1997, and effective September 16.1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Tracy, CA [Revised]

Tracy Municipal Airport, CA
(Lat. 37'41'15" N. long. 121°26'29" W)
Manteca VORTAC
(Lat. 37'50'01" N. long. 121°10'17" W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Tmcy Municipal Airport and within 2.2 miles each side of the Manteca VORTAC 237° radial, extending from the 6.4-mile radius to 4.9 miles southwest of the Manteca VORTAC and within 1.8 miles each side of the 117° bearing from the Tracy Municipal Airport, extending from the 6.4-mile radius to 8.4 miles southeast of the Tracy Municipal Airport and within 1.8 miles each side of the 326° bearing from the Tmcy Municipal Airport, extending from the 6.4-miles radius to 7.7 miles northwest of the Tracy Municipal Airport, excluding that portion within the Stockton, CA, Class E and Livermore, CA, Class E airspace areas, and excluding-that airspace within Restricted Area R2531A.

* * * * *

Issued in Los Angeles, California, on November 7.1997.

Michael Lammes,

Acting Manager, *Air Traffic Division, Western-Pacific Region.*

[FR Doc. 97-30353 Filed 1 l-19-97; 8:45 am]

BILLING CODE 4910-13-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Household Products With Mom Than 50 mg of Elemental Fluoride rnd More Than 0.5 Percent Elemental Fluoride: ● d Modification of Exemption for Oral Prescription Drugs With Sodium Fluoride

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing 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). Examples of such products are some rust removers, toilet cleaners, metal cleaners and etching products. Dental products. such as toothpaste, contain lower levels of fluoride and would not be affected. For consistency, the Commission is also proposing to modify the oral prescription drug exemption for sodium fluoride preparations. Instead of allowing drugs with no more than 264 mg of sodium fluoride per package to be in non-CR packaging as the current rule does, the Commission proposes to allow such drugs with only 50 mg or less of the equivalent of elemental fluoride (110 mg or less of sodium fluoride) per package and no more than the equivalent of 0.5 percent elemental fluoride on a w/v *or* w/w *basis. 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 handling or ingesting a toxic amount of elemental fluoride. The Commission takes this action undu the authority of the Poison Prevention Packaging Act of 1970.

DATES: Comments on the proposal should be submitted no later than February 3. 1998.

ADDRESSES: Comments should be mailed to the Office of the Secretary. Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502. 4330 East-West Highway, Bethesda, Maryland 208 14–4408, telephone (301)504–0800. Comments may also be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov.

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

SUPPLEMENTARY INFORMATION:

A. Background

1. Household Products Containing Fluoride

Many types of household products may contain fluoride in one form or another. Fluorides are ingredients in cleaning products 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 bffluoride, ammonium fluoride, potassium bifluoride, sodium bffluoride, sodium fluoride and sodium fluosilicate. [1] [3] [2]

Many dental products also contain fluorides, but at lower levels.

[1] The percentage of elemental fluoride in any compound is determined by dividing the molecular weight of fluoride (= 19 grams/mole) by the molecular might of the compound (e.g., the molecular weight of sodium fluoride = 42 grams/mole). Sodium fluoride contains 45% elemental fluoride (19/42 x 100 = 45%).

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

Prescription dental products are available with fluoride contents of 0.125–0.5 mg/ml for drops, OS- 1 mg per tablet. 1 mg per lozenge, 0.1–0.9 mg/g for topical rinses (0.01–0.09 percent and 5 mg/g (0.5 percent) for topical gels. Prescription vitamin preparations are also available containing 0.25 to 1 mg elemental fluoride per ml. The highest concentration of elemental fluoride in any such dental product available over-the-counter ("OTC") is 0.15 percent for pastes and powders and 0.5 percent for liquids or gels. In contrast, some household products, particularly metal cleaners and rust removers containing hydrofluoric acid and/or soluble fluoride salts, can have as much as 57 percent elemental fluoride. 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 Requirements for Fluoride-Containing Products

The Commission currently requires CR packaging for oral prescription drugs with fluoride, but it exempts those !n 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). In 1977, the Commission first exempted aqueous solutions of sodium fluoride at that level. In 1980, in response to a petition, the Commission extended the exemption to include liquid and tablet forms. When it issued the exemption, the Commission believed that drugs with sodium fluoride below that level would not cause serious personal injury or illness to children under 5 years of age. The Commission based this decision on the lack of serious adverse human experience associated with such drugs at that time. The level was also partly based on 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. Also at that time, the Food and Drug Administration ("FDA") had determined that an acutely toxic dose of sodium fluoride for a 25 pound (~ 11.4 kg) child was in the range of 56 to 250 mg/kg (equivalent to ~ 23 to 113 mg/kg of elemental fluoride) (42 FR 62363). As discussed below, the Commission is proposing a new level that is based on current information concerning the toxicity of fluoride and would be consistent with the proposed CR requirement for fluoride-containing household products.

The FDA limits OTC packages of toothpaste and tooth powder to no more than 276 mg total elemental fluoride per package. 21 CFR 310.545. However, preventative treatment rinses and gels sold OTC must contain no more than 120 mg *total* elemental fluoride per package. 21 CFR 355.10.

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]

Systemic fluoride poisoning after ingestion or inhalation occurs very rapidly as the fluoride is absorbed into the gastrointestinal ("GI") tract and lungs. Systemic fluoride poisoning can also result from dermal exposure if the exposure is massive or the skin barrier has been destroyed. as with severe bums. 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. Dermal exposure to 6 to 10 percent HF is the lowest concentration range known to cause skin injury in humans. Destruction of tissue under the skin may occur, as may decalcification and erosion of bone. Death from systemic fluoride toxicity has resulted from dermal exposure to 70 percent HF over 2.5 percent of the body surface. [2]

ocular exposure can result in serious eye injury. Exposure to concentrations of 0.5 percent can lead to mild conjunctivitis and greater concentrations can lead to progressively severe results such as immediate corneal necrosis (20 percent solution).

Ingestion of fluoride can result in mild to severe Cl symptoms. Reports suggest that ingesting 3 to 5 milligrams per kilogram of fluoride causes vomiting, diarrhea, and • bdom!nal 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 do not correspond 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 Gl 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. Some of the burns occurred even after the clothing had been washed.[2]

Other reports included that of a 14-month-old child who developed hypocalcemia and hyperfluoridemia (elevated blood fluoride level) and went into cardiac arrest after exposure to a rust remover containing HF. A 2½-year-old child developed respiratory failure and repeated episodes of ventricular tachycardia (rapid heart beat) and fibrillation after ingesting a laundry sour (used in laundry operations to neutralize alkalis or decompose hypochlorite bleach) with sodium fluosilicate. A 28-year-old man died after accidentally drinking floor polish that contained fluosilicate. A 56-year-old man died after ingesting a spoonful of glass etching cream (20% ammonium bifluoride and 13% sodium bffluoride). He had severe burns in his esophagus and stomach, and he suffered cardiac arrest 5 hours after the ingestion.[2]

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 ("IIPI") 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]

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. In another case, an 18-year-old man developed second and third degree burns on his hands after exposure to an automobile water spot remover with HF. His fingers became permanently flexed from damage to the muscle and connective tissue. A 20-year-old male died of cardiac arrest after ingesting one to two ounces of a wheel cleaner with fluoride.121

Three reports in the INDP files involve children under 5 years old who died after ingesting fluoride-containing products. A three-year-old child ingested an unknown product with HP. The second case involved a E-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 HP and 8 percent phosphoric acid.[2]

Since 1995, there have been six additional reports of fluoride poisoning in children under 5 years of age from the wheel cleaning product involved in the death of the 20-year-old man described above. The product contains ammonium bffluoride 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]

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 he 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* outcomes. The AAPCC data 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 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 HP. Of these, 2.88 1 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 bffluoride 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]

D. Level of Regulation for Household Products Containing Fluoride

The Commission is proposing a tie 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 weight-to-volume ("w/v") basis for liquids or a weight-to-weight ("w/w") basis for non-liquids.[1&2] The Commission is especially interested in obtaining information and receiving

[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.

comments on the uses and marketing patterns of glass etching creams.

There is no well defined Iethal dose for fluoride. In the medical literature, one source cites a minimum lethal dose in humans of 71 mg/kg and another specifies a Iethal 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 certainly Iethal dose (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 proposes 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 bums. [1&2]

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 proposed level for household products containing fluoride, the Commission is proposing that the lwel for the oral prescription drug exemption be changed to allow no more than the quivalent of 50 mg of elemental fluoride (110 mg sodium fluoride) per package and 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. The proposed level provides a safety factor to protect sensitive individuals. [1&2]

The Commission does not believe that changing the kvel 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. There is no evidence that any of these products have caused serious injury. The Commission proposes modifying the exemption level so that it is consistent with the regulated level proposed for household products containing fluoride.1 1]

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 preliminarily 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 new manufacturers. [1&2]

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 proposing to modify the existing exemption for such drugs with sodium fluoride to reflect current toxicity data and be consistent with the proposed level for fluoride-containing household products. [1&2]

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 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 by the effective date to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modem 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]

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 preliminarily 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-Mendiy special packaging is currently commercially available for most types of CR packaging. Aerosol and mechanical pump packages should be commercially available in senior-Mendly CR designs within nine months of a final rule.[1,4 & 5] Thus, the Commission proposes that a final rule would take effect nine months after publication of the final rule.

Currently available information indicates that full commercial availability for senior-friendly mechanical pump packages and aerosol overcap packages could take from 9 to 12 months from the date a final rule is issued. If comments on this proposal indicate that manufacturers using mechanical pump packages and aerosol overcap packages need more than 9 months to comply with the rule, the Commission may (1) specify a i-year effective date for these types of packages only. or (2) provide that manufacturers may request a stay of enforcement so they can market their products in conventional packaging for the minimum period needed to obtain an adequate supply of senior-friendly 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.

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]

This assessment reports that the staff is aware of 25 suppliers of products that are in categories of products that may contain fluorides. Fourteen of these companies may be small businesses. It is unclear which of these products actually contain fluorides and are marketed directly to consumers rather than commercial markets. The staff is also aware of 40 suppliers of automotive and household cleaning chemicals and products. Some of these products may contain fluoride.[3] The Commission requests comments from companies that supply fluoride-containing household products. The Commission is particularly interested in comments and information on the likely effect of this proposed rule on small businesses.

Several consumer products containing fluoride are already in CR packaging. For example, senior friendly packaging is used by a small business marketer of a fluoride-containing rust remover packaged in a plastic container with a continuous turn closure. Another small, business, marketing a fluoride-containing glass etching cream, also uses senior-friendly CR packaging. However, the small business marketer of another glass etching product is not currently using CR packaging. A variety of types of senior friendly CR packaging that would be suitable for such products are readily available at prices competitive with non-CR packaging. Similarly, of the three known marketers of fluoride-containing wheel cieanen. one (a large manufacturer) is using CR packaging, while another (a small business) is not. Senior-friendly trigger sprays like those used for this product are available. The incremental cost of a CR trigger is not likely to be large relative to the retail cost of the product.[3]

Based on this assessment. the Commission concludes 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.

Furthermore, the proposed modification in the level for exemption of oral prescription drugs containing sodium fluoride is not likely to affect any currently available prescription drugs. and if such drugs should become available in the future appropriate CR packaging is readily available at prices competitive with non-CR packaging. Therefore, the Commission concludes that the proposed 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.

I. 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 fluoride-containing products.

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 102 1 .5(c) (3). Nothing in this proposed rule alters that expectation. Therefore, because the rule would have no adverse effect on the environment. neither an environmental assessment nor an environmental impact statement is required.

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)(I). In addition, the Federal govemment, or a State or local govemment, 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 proposed 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 proposed 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 proposes to amend 16 CFR pan 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 to revise paragraph (a) (10) (vii) and to add paragraph (a)(27) to read as follows (although unchanged, the introductory text of paragraphs (a) and (10) are included 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 meeting the requirements of § 1700.206) 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 § 1790.15 (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 and 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 SO 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 § 1790.15 (a), (b) and (c).

Dated: November 17.1997.

Sadye E. Dunn,

Secretary, consumer *Product Safety Commission.*

List of Relevant Documents

1. Briefing memorandum from Jacqueline Fen-ante, Ph.D., EH. to the Commission, "Proposed Rule to Rquire 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.

[FR Doc. 97-30555 Filed 11-19-97: 8:45 am]

BILLING CODE 6355-01-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230,240 • d 270

[Release Nos. 33-7475, 34-39321, IC-22884; File No. S7-27-97]

RIN 3235-AG98

Delivery of Disclosure Documents to Households

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing for public comment a new rule under the Securities Act of 1933 to enable issuers and broker-dealers to satisfy the Act's prospectus delivery requirements, with respect to two or more investors sharing the same address. by sending a single prospectus, subject to certain conditions. The Commission is proposing similar amendments to the rules under the Securities Exchange Act of 1934 and the Investment Company Act of 1940 that govem the delivery of annual and (in the case of investment companies) semiannual reports to shareholders. The proposed rule and rule amendments seek to provide greater convenience for investors and cost savings for issuers by reducing the amount of duplicative information that investors receive.

DATES: Comments must be received on or before February 2.1998.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz. Secretary. Securities and Exchange Commission, 450 5th Street, N.W., Stop 6-9, Washington. D.C. 20549. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. All comment letters should refer to File No. S7-27-97; this file number should be included on the subject line if E-mail is used. Comment letters will be available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, N.W.. Washington, D.C. 20549. Electronically submitted comment letters also will be posted on the Commission's Internet web site (http://www.sec.gov).

FOR FURTHER INFORMATION CONTACT: Marilyn Mann. Senior Counsel, at (202) 942-0690, Office of Regulatory Policy, Division of Investment Management, Stop 10-2, or Elizabeth M. Murphy, Special Counsel, at (202) 942-2900, Office of Chief Counsel, Division of Corporation Finance. Stop 4-2, Securities and Exchange Commission. 450 5th Street, N.W.. Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: The Commission today is requesting public comment on proposed rule 154 under the Securities Act of 1933 (15 U.S.C. 77a) (the "Securities Act") and proposed amendments to rules 14a-3 (17 CFR 240.14a-3).14c-3 (17 CFR 240.14c-3) and 14c-7 (17 CFR 240.14c-7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a) (the "Exchange Act"), and rules 30d-1 (17 CFR 270.30d-1) and 30d-2 (17 CFR 270.30d-2) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the "Investment Company Act").

Table of Contents

TAB B

Colgate
Oral Pharmaceuticals

22 January 1998

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

E-Mail: cpsc-os@cpsc.gov

Reference: Proposed 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."

Dear Sir or Madam:

I am writing to comment on the above mentioned proposed Consumer Product Safety Commission rulemaking.

In both the summary and the text (16 CFR 1700.14(10)(vii)) of this rulemaking. the Commission proposes to allow sodium fluoride drug preparations to be packaged in non Child Resistant Closure (CRC) packages if they contain 50 milligrams or less of the equivalent of elemental fluoride (110 milligrams or less of sodium fluoride) per package **and** no more than the equivalent of 0.5 percent elemental fluoride on a w/v or w/w basis.

This wording would seem to indicate that both criteria (total elemental fluoride per package and elemental fluoride concentration) would have to be met in order to qualify for the exemption.

However. in the preamble to the proposed rule (section E), the Commission states that it ". . . ..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 ion.

This statement indicates that only one (not both) of the criteria (total fluoride [F^-] ion or concentration) would have to be met in order to qualify for the exemption. Therefore, I contacted the Consumer Product Safety Commission for clarification.

Dr. Jacqueline Ferrante clarified that only one (not both) of the criteria needs to be met to qualify for the exemption.

Therefore, I would like to request that the wording in the text of the rule be modified as follows at 16 CFR 1700.14(10)(vii): "....sodium fluoride drug preparations....,containing not more than 110 mg sodium fluoride...per package and/or not more than a concentration of 0.5 percent elemental fluoride...."

Thank you for allowing me the opportunity to comment on this proposed rulemaking.

Please feel free to contact me at (972) 720-6003 should you have any questions on this comment.

a subsidiary of *Colgate-Palmolive Co.*
14335 Gillis Road, Dallas, TX 75244 (972) 233-2800 Fax (972) 239-6854

Sincerely,

Eugenie C. Acosta

Ms. Eugénie Acosta
Manager, Regulatory Affairs
Colgate Oral Pharmaceuticals

American
Dental
Association

David A. Whiston, D.D.S.
President
211 East Chicago Avenue
Chicago, Illinois 60611-2678
(312) 440-2871
Fax (312) 440-7488
whistond@ada.org

ADA.

CPSA 6 (b)(1) Cleared
No Mfrs/Privlblrs or
Products Identified
Accepted by
Firms Notified.
Comments Processed.

February 6, 1998

Sadye Dunn
Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway, Room 502
Bethesda. Maryland 20814-4408
Washington, DC 20207

SUBJECT: Consumer Product Safety Commission, 16 CFR Part 1700, Proposed Rule: Requirements For Child-Resistant Packaging; Household Products With More Than 50 mg of Elemental Fluoride and More than 0.5% Elemental Fluoride; and Modification of Exemption for Oral Prescription Drugs With Sodium Fluoride, Federal Register Vol. 62, No. 224, November 20, 1997, pages 61928-61933.

Dear Secretary Dunn:

The official position of the American Dental Association (ADA) is that it dues not object to the Consumer Products Safety Commission (CPSC) changing its requirements for child-resistant packaging for fluoride-containing products used in the home, as shown in the following two proposals outlined in the Proposed Rule:

Proposal 1. Requiring child-resistant packaging for household products (which include non-dental and over-the-counter dental products) containing a) more than the equivalent of 50 mg of elemental fluoride (fluoride ion), *and* b) more than the equivalent of 0.5% elemental fluoride (on a w/w for a solid or w/v for a liquid basis). Both criteria must be met before child-resistant packaging would be mandated.

Proposal 2. Modifying the oral prescription drug exemption for sodium fluoride preparations (e.g. fluoride supplements, fluoride/vitamin preparations). Instead of allowing drugs with no more than 264 mg sodium fluoride (120 mg elemental fluoride) per package to be in non-child-resistant packaging, as the current rule does, the CPSC would require child-resistant packaging only for fluoride-containing products with a) more than the equivalent of 50 mg of elemental fluoride (fluoride ion), *and* b) more than tk equivalent of 0.5% elemental fluoride (on a w/w for a solid or w/v basis for a liquid). Both criteria must be met before child-resistant packaging would be mandated.

The CPSC states that dental products contain lower levels of fluoride and therefore would not be affected by these proposals.

The ADA is in agreement with the CPSC's belief, as expressed both in the background to the proposed rule and in the wording of Proposals 1 and 2 above. that currently-marketed. fluoride-containing, over-the-counter and prescription dental products, intended for home use, have not been shown to pose a significant safety hazard to young children, and that these dental products, therefore, do not need child-resistant packaging. In addition, the ADA notes that there are no currently-marketed dental products that meet both of the proposed criteria for child-resistant packaging.

The ADA understands the CPSC's wish to regulate non-dental, fluoride-containing products (such as cleaning products for metal, tile. brick, cement. wheels, radiators, siding, toilets, ovens, and drains, and other items including rust and water stain removers, silver solder and other welding fluxes, etching compounds, laundry sour, air conditioner coil cleaners and floor polishes) used in the home to help prevent accidental injury to young children Because such products arc not related to dentistry, however, the ADA will not comment on this aspect of the proposed rule.

Sincerely,

David A. Whiston D.D.S.

David A. Whiston, D.D.S.
President

DAW:JH:pg

CPSA § (b)(1) Cleared
No Mfrs/PrivateLbls or Products Identified
Excepted by
Firms Notified.
Comments Processed.

ART & CREATIVE MATERIALS INSTITUTE

CERTIFYING SAFETY AND QUALITY SINCE 1940

THE ART & CREATIVE MATERIALS INSTITUTE, INC.
100 Boylston Street, Suite 1050
Boston, MA 02116
Tel.: 617/426-6400
Fax: 617/426-6639

Deborah M. Fanning, CAE
Executive Vice President

February 23, 1998

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

RE: NOTICE OF PROPOSED RULEMAKING (NPR) FOR HOUSEHOLD PRODUCTS CONTAINING MORE THAN 50 MG OF ELEMENTAL FLUORIDE AND MORE THAN 0.5% ELEMENTAL FLUORIDE
62 Federal Register, 61928 (November 20, 1997)

In response to the Notice of Proposed Rulemaking (NPR) on the extension of the Poison Prevention Packaging Act (PPPA) by the Consumer Product Safety Commission (CPSC) to certain household products containing more than 50 mg of elemental fluoride and more than 0.5% elemental fluoride, The Art and Creative Materials Institute, Inc. (ACMI) is pleased to submit the following comments. ACMI is an international non-profit association of manufacturers of art and creative materials who are committed to providing non-toxic products to children and products that have been evaluated for toxicity risks, and, if any, labeled with cautionary warnings and safe use instructions for adult consumers. ACMI's certification program began evaluating children's art materials as non-toxic in 1940 and continues to this day; its program was expanded in 1982 to evaluate and properly label adult art materials.

CP NONTOXIC AP NONTOXIC HEALTH LABEL

In previous comments, ACMI supported the extension of PPPA regulations to petroleum distillates, hydrocarbons and terpenes that present an aspiration risk as listed in the NPR at the percentage compositions contained in the FHSA regulations and at a viscosity of less than 100 SUS at 100° F. In the case of art materials, this would extend PPPA regulations to any art material containing 10% or more of xylene, toluene, petroleum distillates, and D-Limonene. FHSA and its regulations also require DANGER warnings for materials that are corrosive or highly toxic. We also recommended the extension to products that require such a DANGER warning and that present an aspiration hazard. Art materials that are currently labeled with a DANGER warning because they are corrosive or are considered highly toxic contain 0.075% or more ammonium bifluoride, 30% or more of calcium chloride, or 0.25% or more of sodium fluoroborosilicate and include glass etching creams, some ceramic glazes, and some ceramic thickeners. Therefore, we certainly support the current NPR to extend the PPPA regulations to cover household products containing more than 50 mg of elemental fluoride and more than 0.5% elemental fluoride.

As a major contributor to the development of ASTM D-4236, the pioneering chronic hazard labeling standard for art materials, the development of LHAMA, and a member of the Poison Prevention Week Council, ACMI is committed to the provision of safe products and information to consumers of its members' products and is pleased to submit these comments for consideration by CPSC. ACMI appreciates the extension granted to submit these comments.

Respectfully submitted,

Deborah M. Fanning

Deborah M. Fanning, CAE
Executive Vice President

Of Counsel: Neville, Peterson & Williams
80 Broad Street, 34th Floor
New York, NY 10004

cc: Woodhall Stopford, M.D.
Jacqueline Ferrante

66 01<
4/3/98

CMA

CHEMICAL MANUFACTURERS ASSOCIATION

COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR

March 30, 1998

Office of the Secretary
Consumer Products Safety Commission
4330 East West Highway
Room 502
Bethesda, MD 20814

RE: Proposed Rule: Child-Restraint Packaging for Household Products with Fluoride

Dear Sir/Madam:

The Chemical Manufacturers Association Hydrogen Fluoride (HF Panel) is pleased to submit these comments in response to the Consumer Product Safety Commission's (CPSC) proposal to establish child-restraint packaging requirements for household products containing elemental fluoride above specified amounts or concentrations. 62 Fed. Reg. 61928 (Nov. 20, 1997). The HF Panel is an industry group concerned with issues relating to the safe use and handling of anhydrous hydrogen fluoride and hydrofluoric acid. Our membership is composed of manufacturers, transporters, and industrial users of HF.1

The CPSC is proposing to require child-restraint (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). Examples of such products include rust removers, toilet cleaners, metal cleaners and etching products. The CPSC also is proposing to modify the oral prescription drug exemption for sodium fluoride preparations. Current rules allow drugs with no more than 264 mg of sodium fluoride per package to be in non-CR packaging. To be consistent, the CPSC now proposes to allow such drugs with only 50 mg or less of the equivalent of elemental fluoride (110 mg or less of sodium fluoride) per package and no more than the equivalent of 0.5 percent elemental fluoride on a w/v or w/w basis. The CPSC has made a preliminary determination that child-resistant packaging is necessary to protect children under 5 years of age from injury and illness resulting from handling or ingesting toxic amounts of elemental fluoride.

1 The Hydrogen Fluoride Panel includes 3M Company, AlliedSignal, Inc., Aluminum Company of America, Chemtech Products, Inc., Daiken American Inc., Dupont, Elf Atochem, N.A., General Chemical, Industrial Quimica de Mexico, S.A. de C.V., LaRoche Industries Inc., LCI/Norfluor, Occidental Chemical Corporation, OSRAM Sylvania Inc., and Quimica Fluor S.A.

The HF Panel supports the CPSC's efforts to encourage the safe handling and use of products containing fluoride. More specifically, the Panel supports the CPSC's current proposed rule and believes it may help prevent injuries to small children from the mishandling of certain fluoride-containing consumer products.

The Panel appreciates the work that the CPSC has done relating to the proposed rule. If you have any questions concerning these comments, please call Elizabeth Festa Watson, Manager of the Hydrogen Fluoride Panel at (703) 741-5629.

Sincerely yours,

Courtney M. Price
Vice President, CHEMSTAR

TAB C

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

OCT – 9 1997

TO : Jacqueline Ferrante, Ph.D., Pharmacologist, Division **of** Health Sciences

THROUGH : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Epidemiology. and Health Sciences (EH)

Marilyn L. Wind, Ph.D., Director, Division of Health Sciences Scientific Coordination

FROM : Susan C. Aitken, Ph.D., Pharmacologist, Division of Health Sciences

SUBJECT : Update on Injuries Due to Products Containing Fluoride

Staff recently learned of additional injuries due to household products containing fluoride salts or hydrofluoric acid. One fatal incident involved the ingestion of a wheel cleaner containing ammonium fluoride and ammonium bifluoride salts by a 3-year-old girl (August 9, 1997). A series of injuries due to this same wheel cleaner were reported in a previous memorandum discussing the toxicity of products containing elemental fluoride (CPSC, 1997). An In-Depth-investigation (IDI) of this case is complete with the exception of the coroner's report. A second incident involved the death of a 38-year-old male following the unintentional ingestion of one-half cup of rust remover containing ammonium bifluoride (Litowitt et.al., 1997). A third incident involved the lethal ingestion of a rust remover containing hydrofluoric acid and ammonium bifluoride by a 1 g-month-old girl (July 22, 1997). An IDI in this third case is complete with the exception of some official records. A fourth incident involved the ingestion of a small quantity of a rust remover, bearing the same trade name as the product implicated in the third incident and with a similar description of the dispenser, by an 18-month-old girl.

A briefing package recommending a special packaging standard under the Poison Prevention Packaging Act (PPPA) for products containing more than 0.5 percent elemental fluoride and more than 50 mg elemental fluoride per package is now before the Commission. The incidents reported here support the need for such a special packaging standard to protect young children from serious personal injury and illness **due to** handling, using, or ingesting household products containing amounts of elemental fluoride exceeding the recommended levels for regulation. Details of these incidents are reported below.

Incident 1. A previously healthy 3-year-old girl accessed an 8 ounce (oz) pump spray bottle of wheel cleaner momentarily left on the kitchen counter after use. Both parents were outside for a brief period and the actual ingestion was

unwitnessed. Although the poison control information indicates the child obtained the solution from a cup, the testimony of the father indicates the child obtained the liquid from the original container. It is unknown whether the child, who was reportedly clever, unscrewed the pump spray, drank some of the liquid from the container, and then replaced the pump; the child sprayed liquid directly into her mouth; or the child sprayed liquid into another container and then drank it. The pump was still on the bottle after the ingestion. However, when the bottle was photographed at the time of the CPSC investigation, the pump was missing.

The child complained of stomach pain and a sibling indicated she drank some of the wheel cleaner. After administering water, the child vomited. The father immediately transported her to an emergency room (ER), arriving about 20 minutes post-ingestion. By that time, the child was vomiting intermittently, experiencing a drop in blood pressure, was cyanotic, and minimally reactive. The emergency staff immediately intubated to maintain respiration. However, blood pressure continued to fall and no pulse was detected. About 20 minutes after arrival, the ER personnel consulted with the local poison control center, confirmed that the ingested product appeared to be a fluoride solution, and, while continuously administering cardio-pulmonary resuscitation (CPR), the staff commenced an intravenous infusion of calcium gluconate and calcium chloride. Continued aggressive treatment failed to restore a pulse, heart rhythm and breathing were irregular, and the child was increasingly cyanotic. The child went into cardiac arrest, attempts to revive her were not successful, and CPR was terminated approximately one hour after arrival at the ER. Although the laboratory conducting post-mortem toxicology tests did not have the capability of measuring serum or urinary fluoride, other autopsy results will become available in the near future.

Incident 2. After ingesting approximately one-half cup of rust remover containing ammonium bifluoride, the 38-year-old victim presented to an emergency room hospital facility. After one episode of vomiting, he was asymptomatic at 1-1/2 hours post-exposure. However, 3-1/2 hours post-ingestion, he experienced sudden cardiac arrest. Although resuscitation efforts were transiently successful and calcium chloride was administered, a series of subsequent cardiac arrests resulted in death approximately 4 hours post-ingestion.

Incident 3. The parents were in the process of moving into a mobile home. A bottle of carpet tust remover containing hydrofluoric acid and ammonium bifluoride had been left in the mobile home by the previous owner along with other cleaning chemicals. The parents had packed the chemicals left behind in a box, and placed this box in a closet. However, the bottle of rust remover was overlooked and was left in a box on the living room floor. Apparently the 19-month-old child awoke at about 9 AM while the parents were asleep and drank an undetermined amount from the bottle. The child, crying and coughing, awoke her parents and a 3-year-old brother told them she had drunk from the bottle. The parents took the child to

a neighbor's home where the neighbor attempted to give her some milk. However, after learning what she had ingested, the neighbor suggested the child should be taken to the hospital. The child died shortly after.

This incident is currently under investigation by the local Sheriff's Department and the container is being held in evidence for possible criminal proceedings. The container is described as a whitish plastic bottle about 6-1 /2 inches high and 2-5/8 inches in diameter with a protrusion about 1 inch high and 1 inch in diameter for dispensing. The sheriff's investigative report indicated the protrusion resembled that of an infant's drinking cup. The sheriff's full report includes a description of the labeling on the rust remover, and this report plus additional information is expected shortly. Staff also expects further information on the product formulation to become available.

Incident 4. The parents of an 18-month-old-child were building an addition on their home, and placed some of their tools and supplies on the kitchen counter the evening prior to the incident. While waiting for breakfast the next morning, the victim climbed onto a chair to access the counter and found a bottle of rust remover (the same trade name as reported in incident 3). The container is described as a plastic bottle having a long narrow plastic spout for dispensing the product. The cap covering the spout was not in place when the child drank an unknown amount of the rust remover. The child began to cough, her mother rushed in from the next room, and a 5-year-old sibling informed the mother that the victim drank some of the rust remover. Poison Control advised the mother to give the child water and take her to a hospital. Treatment involved an unspecified blood test, an x-ray to ascertain if any of the product had entered the lungs, and observation for a short time. The child was released the next day. The mother believed the child ingested less than 1 ounce. One ounce equals approximately 30 milliliters (ml). However, if the product was in fact identical to the toxic product that proved fatal in incident 3, staff suspects the child ingested much less than 30 ml and probably took no more than one swallow (approximately 5 ml). The child may also have spit out some of the material.

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TAB D

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

APR 20 1998

TO : Jacqueline Ferrante, Ph.D., Pharmacologist, Division of Health Sciences

THROUGH : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Epidemiology and Health Sciences (EH) MAD

Marilyn L. Wind, Ph.D., Director, Division of Health Sciences Scientific Coordination MLW

FROM : Susan C. Aitken, Ph.D., Pharmacologist, Division of Health Sciences SCA for SCA

SUBJECT : Injuries Due to Products Containing Fluoride

The Commission recently published a notice of proposed rulemaking (NPR)[1] under the Poison Prevention Packaging Act (PPPA) which would establish a special packaging standard for household products containing more than 0.5 percent and more than 50 milligrams elemental fluoride. The briefing package "Proposed Rule to Require Child-Resistant Packaging for Household Products with Fluoride"[2] and an addendum to the briefing package "Update on Injuries Due to Products Containing Fluoride"[3] documented several injuries that provided support for the NPR. This memorandum provides additional injury information acquired since the staff prepared the addendum. In this memorandum, staff of the Division of Health Sciences (HS) review CPSC data bases (June 1, 1997 through February 28, 1998) and the 1996 Toxic Exposure Surveillance System (TESS) data base maintained by the American Association of Poison Control Centers (AAPCC) for reports of exposures to products containing elemental fluoride.

NEISS Incidents - Burns

CPSC's Injury and Potential Injury (IPII), In-Depth Investigation (INDP), and Death Certificate (DTHS) data bases contained no reports of incidents involving household products containing elemental fluoride. However, CPSC's National Electronic Injury Surveillance System (NEISS) data base contained several reports of injuries due to either hydrofluoric acid (HF) or soluble fluoride salts. The toxicities of these forms of fluoride are almost identical and essentially are dependent only on the actual amount of elemental fluoride present. NEISS data show six adults experienced burns to fingers, hands, or arms following use of HF-containing cleaners. A 52-year-old female suffered chemical burns to both hands when using rust remover to clean windows and a 76-year-old male, a 42-year-old male, a 43-year-old male, and a 49-year-old male suffered similar burns after using various cleaners containing HF. One 50-year-old woman was

hospitalized overnight due to burns to her fingers after using a rust remover to clean the metal legs of a table. In this case, and at least one of the other cases, the individuals were not using gloves. In addition to these incidents, an 18-year-old female suffered chemical burns to her abdomen and back after using rust remover to remove stains from a shirt, washing the shirt, and wearing it.

NEISS Incidents - Ingestions

Three NEISS incidents involved accidental ingestion of rust removers containing HF by children less than 5-years-old. A 12-month-old male may have ingested some material from an open can of rust remover. He also spilled some on his right leg, causing burns. A 12-month-old female was found pouring rust remover into a cup. Although the parents did not believe the child actually ingested any of the product, the child did experience a blistered lip. In the third case, a 2-year-old male ingested an undetermined amount of rust remover. All three individuals were treated and released.

Two NEISS incidents involving a wheel cleaner containing ammonium fluoride salts were identified. The wheel cleaner in question was recalled in August, 1997 following the death of a three-year-old child after accidental ingestion of the product. In the first case, a 2-year-old male sprayed the cleaner in his mouth. The child was treated and released. In a second case, a 21-month-old male was hospitalized after an accidental ingestion. The staff is investigating this incident for more details. In addition, an investigation of another incident could not establish whether the product in question was the wheel cleaner. The product may have the same brand name but actually be a solvent-based cleaner used on vinyl and tires. Apparently, the sibling of the 3-year-old victim sprayed the cleaner on the child's hair and hands and possibly into her mouth. However, the parent indicated the child was not burned but was hospitalized overnight for observation after becoming slightly ill.

Three other NEISS injuries to children less than 5-years-old involved products which may or may not have contained HF. All three incidents are now under investigation. At this time, no further details are available.'

The types of injuries reported above are similar to those reported in previous memoranda[2,3]. Adults tend to experience burns to the hands during planned use of products containing elemental fluoride. Injuries to children tend to be associated with attempted ingestions which can result in accidental burns.

AAPCC Incidents

Staff also reviewed the 1996 TESS data. These data only isolate fluoride-containing products for hydrofluoric acid, rust removers containing hydrofluoric acid, and various types of anti-caries treatments such as fluoride toothpastes, fluoride mouthwashes, prophylactic treatments with tablets, pastes, and powders (captured as fluoride under electrolytes/minerals), and vitamin supplements (captured as various types of vitamins containing fluoride). Several other classes of products, notably cleaners, may contain unspecified acids or fluoride salts and may be coded as acidic cleaning products or other/unknown cleaning products. Therefore, these data represent only an estimate and possible lower bound and cannot establish the actual number of ingestions of fluoride products.

Injuries due to fluoride-containing products are shown in Table 1 (children < 5-years-old, ingestions) and Table 2 (all ages, all routes of exposure). No fatalities or major injuries occurred in children less than 5-years-old who were exposed to HF or HF-containing rust removers. One major injury was reported due to ingestion of fluoride in the form of electrolytes/minerals In general, household products containing HF or fluoride salts appear to pose a more serious risk to the population as a whole than do anti-caries treatments containing fluoride. Table 2 indicates that moderate to major consequences developed in 14.2 percent of exposures to household products containing elemental fluoride in the form of HF as opposed to 0.5 percent of exposures to anti-caries treatments containing elemental fluoride. This pattern is almost identical to that reported in the original toxicity review of fluoride-containing products (12.8 percent for household products containing HF versus 0.4 percent for anti-caries treatments)[3].

HS staff reemphasizes that the form of elemental fluoride, whether HF or soluble fluoride salt, is irrelevant to degree of toxicity. In either case, toxicity is determined by the absolute amount of elemental fluoride. Previous memoranda provided data supporting the conclusion that products containing more than 0.5 percent and more than 50 mg elemental fluoride could cause serious personal injury or illness to children less than 5-years-old. This memorandum provides additional evidence supporting both the toxicity of household products containing concentrations and amounts of elemental fluoride above the proposed level for regulation and the general lack of toxicity of anti-caries products that contain 0.5 percent or less elemental fluoride.

TABLE 1. AAPCC TESS DATA
(1996, accidental ingestions by children < 5)

		OUTCOME			
	Total	minor	moderate	maior	death
HF Household Products					
Hydrofluoric Acid (HF)	48	14	1	0	**0**
Rust Remover (HF)	88	20	3	0	**0**
Total HF Household Products	136	34	4	0	**0**
Anti-caries Treatments					
Mouthwash + F	904	35	3	0	0
Toothpaste + F	4,099	501	13	0	0
Electrolytes/ Minerals	2,374	237	2	1	0
Vitamins + F	1,367	29	1	**0**	**0**
Total Anti-caries Treatments	8,744	802	19	**1**	**0**

Ingestion refers to cases where the material enters the mouth, and includes ingestions accompanied **by** aspiration. **Minor Symptoms -** The patient exhibited some minimal signs or symptoms which resolved rapidly. **Moderate Symptoms -** The patient exhibited signs or symptoms that were more pronounced, prolonged, or of a systemic nature which usually required some form of treatment. Symptoms were not life threatening and the patient returned to a pre-exposure state of well-being with no residual disability or disfigurement. **Major Symptoms -** The patient exhibited some symptoms which were life-threatening or resulted in disfigurement or residual disability.

TABLE 2. AAPCC TESS Data
(1996, all ages, all routes of exposure)

	Total	<6	Minor	Moderate	Major	Death
HF Household Products						
HF	1,480	121	606	391	21	2
HF Rust Remover	1,464	133	663	351	6	2
Total HF Household Products	2,944	254	1,269	742	27	4
Anti-caries Treatments						
Mouthwash + F	1,483	1,061	82	5	0	0
Toothpaste + F	5,442	4,454	892	37	1	0
Electrolytes/ Minerals	3,741	3,283	435	14	1	3
Vitamins + F	1,921	1,535	43	3	0	0
Total Anti-caries Treatments	12,587	10,633	1,452	59	2	0
Total	15,531	10,887	2,721	801	29	4

Definitions of outcome are as previously described in Table 1.

REFERENCES:

[1] CPSC. Proposed 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". Federal Register 62(224):61928-61933. November 20, 1997.

[2] 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.

[3] Memorandum from Susan C. Aitken, Ph.D., EH, to Jacqueline Ferrante, Ph.D., EH, "Toxicity of Household Products Containing Fluoride", August 4, 1997.

TAB E

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: 08 APR 1998

TO : Jacqueline N. Ferrante, Ph.D., EH
Project Manager, Fluorides

Through: Warren J. Prunella, AED, EC

FROM : Marcia P. Robins, EC
(504-0962)

SUBJECT: Final Rule: Child-Resistant Packaging For Household Products Containing Fluorides

The Regulatory Flexibility Act (RFA [PL 96-3451]) generally requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities, when a general notice of proposed rulemaking is published in the *Federal* Register. However, under section 605, no such analysis is required if the Commission certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

On November **20,** 1997, CPSC published a Notice of Proposed Rulemaking (NPR) 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 or weight-to-weight basis per package.) In this notice the Commission concluded that the proposal would not have a significant economic effect on a substantial number of small businesses or other small entities.

This conclusion was based primarily on the fact that various types of senior-friendly CR packaging suitable for household products containing fluorides are available at prices competitive with nonCR packaging. Thus, costs should not be burdensome to current manufacturers of fluoride-containing products or an entry barrier for future small business marketers. The CPSC staff had observed a number of consumer products containing fluorides in senior friendly CR packaging. The requirement would not affect costs for companies that are already voluntarily providing such CR packaging. Finally, there are no recordkeeping or reporting requirements under the PPPA.

As proposed, the final rule would also modify the current exemption for oral prescription drugs containing sodium fluoride so that it would be consistent with the level proposed for household products. This modification is not likely to affect any currently available prescription drugs. If such drugs should become available in the future, appropriate CR packaging is readily available at prices competitive with nonCR packaging.

A copy of the proposed rule was sent to individual businesses, many of which were small, that may sell fluoride-containing products. However, the public comments on the proposed rule provided no additional information regarding potential adverse impacts on small businesses or other small entities. Therefore, the staff concludes that the rule is not expected to have any significant adverse economic effects on industry or the public.

TAB F

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

3/10/98

TO: Jacqueline N. Ferrante, Ph.D., Project Manager, Fluoride, Division of Health Sciences

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director for Epidemiology and Health Sciences MAD

Marilyn L. Wind, Ph.D., Director, Division of Health Sciences, Directorate for Epidemiology & Health Sciences MLW

FROM: Charles Wilbur, Consumer Safety Officer CW
Division of Health Sciences, (504-0477, ext. 1204)

SUBJECT : Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Special Packaging for Products Containing Fluoride.

The attached evaluation summarizes the Health Sciences determinations of technical feasibility, practicability, and appropriateness for the final rule for fluoride containing household products.

PPPA

FINAL RULE

FLUORIDE

TECHNICAL FEASIBILITY,

PRACTICABILITY,

AND

APPROPRIATENESS

Charles J. Wilbur

MARCH 1998

DIRECTORATE FOR EPIDEMIOLOGY & HEALTH SCIENCES

DIVISION OF HEALTH SCIENCES

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SUMMARY

Directorate for Epidemiology and Health Sciences staff conclude that findings can be supported that special packaging requirements for products containing fluoride are technically feasible (can be produced), practicable (lends itself to techniques of mass production), and appropriate (compatible with the substances contained within the package), for the following:

Products using continuous threaded, snap reclosable, aerosol, and trigger sprayer dispensing child-resistant packaging (,CRP) require an effective date of nine months. A temporary stay of enforcement can be requested if additional time is needed to provide adequate commercial quantities or for small companies converting to senior friendly CRP. Some Poison Prevention Packaging Act (PPPA) regulated substances presently are in these types of Senior Adult Use Effectiveness (SAUE) special packaging. Adequate supplies of CRP are available or can be made available.

Currently PPPA regulations exempt oral prescription drugs, in liquid and tablet forms, that contain no more then 264 mg sodium fluoride. To maintain consistency with the proposed level the staff recommends the exemption level be changed to no more than 110 mg sodium fluoride or no more than a concentration of 0.5 percent on a w/v basis for liquids or a w/w basis for nonliquids. This change is not expected to affect the technical feasibility, practicability and appropriateness findings, as it is not expected to impact currently exempted prescription dental products or OTC dental products.

INTRODUCTION

To require that fluoride containing products at the proposed level be packaged in CRP the Commission must find that CRP is:

- o Technically Feasible - Technology exists to produce packaging conforming to the standards, see 16 CFR 1700.15. Products that must be in aerosol form may be exempt from the senior adult use effectiveness requirements, see 16 CFR 1700.15(b),(2), ii.

- o Practicable - Special packaging complying with the standards, can be produced using modern mass production and assembly line techniques.

- o Appropriate - Packaging complying with the standards, adequately protects the integrity of the substance and does not interfere with its intended storage or use.

TECHNICAL FEASIBILITY

Fluoride containing oral Rx drugs are presently regulated under the PPPA. Most Over-The-Counter (OTC) fluoride containing products are packaged in various sizes of containers with non-CR continuous threaded closures. Other known products are packaged in aerosols and mechanical pumps.

Various types and designs of senior friendly CR packaging can be obtained, see ASTM D3475, Standard Classification of Child-Resistant Packages'. Each type of packaging is addressed below:

CONTINUOUS THREADED RECLOSABLE CR PACKAGING: Two manufacturers are presently using a senior friendly ASTM IA design package'? In addition various designs of senior friendly continuous threaded (screw) type reclosable CR packaging are readily available. ASTM in its Standard Classification of Child-Resistant Packages lists several designs of type I packages that are senior friendly. The majority of fluoride products use or can use this type of CRP.

SNAP RECLOSABLE CR PACKAGING: There is at least one powdered fluoride containing product. We don't know what type of packaging it is in as we were unable to obtain a sample. However, the snap type of CRP is typically used for OTC nonliquid products, i.e., tablets, capsules, powders, etc. There are available various designs of senior friendly snap type reclosable CR packaging. ASTM in its Standard Classification of Child-Resistant Packages lists several designs of type III packages that are senior friendly.

AEROSOL MULTIPLE APPLICATION CR PACKAGING: We know at least one fluoride product uses a non-CR aerosol type package[4]. One product manufacturer of another regulated product is presently using a CR aerosol overcap that is senior friendly'. Two overcap manufacturers have supplied SF protocol test data[6,7] and are in various stages of developing additional sizes of a senior friendly package[8,9]. There are other designs of aerosol overcaps that may be made senior friendly. ASTM in its Standard Classification of Child-Resistant Packages lists designs of type VII packages that can be made senior friendly.

TRIGGER SPRAYER MECHANICAL DISPENSER CR PACKAGING: We know of some fluoride products that use non-CR trigger mechanical pump dispensing mechanisms[10,11]. One product uses a senior friendly CR trigger mechanical pump mechanism that can be permanently attached to the bottle[12]. The supplier of senior friendly CR trigger mechanical pumps supplied the Commission with passing SF protocol test results[13]. This CRP manufacturer can provide this packageto the product manufacturers[14]. There are other designs of trigger sprayers that may be made senior friendly. ASTM in its Standard Classification of Child-Resistant Packages lists designs of type IX packages that can be made senior friendly.

The staff believe that data support the finding that special packaging for fluoride containing products that require CR continuous threaded (screw), snap, aerosol and trigger sprayer packaging are technically feasible.

PRACTICABILITY

Information is available to support the finding that the special packaging of fluoride containing products is practicable.

CONTINUOUS THREADED (CT) AND SNAP RECLOSABLE CR PACKAGING: These types of senior friendly CRP are presently being used by some companies for regulated products, i.e., two fluoride products use CT special packaging. Companies have implemented assembly line and mass production techniques in their manufacturing process for both the CT and snap CRP. This shows that it is practicable to package regulated products in special packaging. No major problems are anticipated in this change from the manufacturing standpoint. Frequently manufacturers can incorporate CR packaging into their existing packaging lines.

AEROSOL MULTIPLE APPLICATION CR PACKAGING: Two known product manufacturers are in commercial production with a senior friendly aerosol overcap. Information is available from two CR packaging manufacturers that this type of senior friendly special packaging can be made commercially available. Both manufacturers supply their CR overcap commercially for other similar products. This special package can be implemented into most product manufacturers assembly line. No major problems are anticipated in using special packaging from the production manufacturing process.

TRIGGER SPRAYER MECHANICAL DISPENSER CR PACKAGING: One known fluoride product manufacturer is currently using a senior friendly CR trigger sprayer for their product. No changes are necessary to the assembly line and mass production technique in the manufacturing process. This shows that it is practicable to package fluoride containing products in trigger sprayer type special packaging. No major problems are anticipated in using CR packaging from the manufacturing standpoint.

APPROPRIATENESS

CONTINUOUS THREADED, SNAP RECLOSABLE AND TRIGGER SPRAYER DISPENSER CR PACKAGING: Some companies are presently using these types of senior friendly special packaging for their products, i.e., two fluoride products use a CT and one a trigger sprayer type special package. Most companies can use existing CR packaging designs and materials that have proven not to be detrimental to the integrity of the substance and have not interfered with its storage or use for these types of CRP. Product shelf-life, and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

AEROSOL MULTIPLE APPLICATION CR PACKAGING: The CR overcap method of packaging has successfully been used by other product manufacturers for their products, and two have a senior friendly overcap. The overcap CR concept does not affect the integrity of the substance or interfere with its storage or use. The CR overcap is separate from the product container. Product shelf-life, and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

Staff, therefore, believe that the data support the finding that special packaging for fluoride containing products are appropriate.

EFFECTIVE DATE

Information received from the packaging manufacturers confirm that most fluoride-containing products can be packaged in senior-friendly CRP in nine months.

CONTINUOUS THREADED AND SNAP RECLOSABE CR PACKAGING: Adequate supplies of Senior Friendly special packaging are available for products requiring continuous threaded and snap reclosable packaging.

AEROSOL MULTIPLE APPLICATION CR PACKAGING: Two major aerosol overcap CRP manufacturers have supplied the Commission with information indicating that their aerosol overcap CRP has passed the senior friendly requirements under the PPPA. Both have supplied confirming protocol test data. One supplier confirmed the need for nine months to one year to make available commercial quantities for the market. Time is needed to provide additional sizes and provide adequate commercial quantities for the market.

TRIGGER SPRAYER DISPENSER CR PACKAGING. One major mechanical trigger pump manufacturer has provided the Commission with protocol test data indicating that their mechanical pump CRP has passed the senior friendly and child-resistant effectiveness requirements under the Poison Prevention Packaging Act (PPPA). However, they need nine months to one year to make available commercial quantities for the market. Time is required for obtaining new tools, purchasing molds, conducting protocol tests, etc.

Senior friendly CRP, e.g., mechanical pump, aerosol overcap, snap and continuous threaded CRP, is available to meet an effective date of nine months for most fluoride containing products. If some individual companies have difficulties in obtaining adequate senior friendly CRP, they can apply to the Commission for a stay of enforcement for a minimum period to market their products in conventional packaging until they can obtain an adequate supply of senior friendly CRP.

CONCLUSION

The staff concludes that data support the findings that ASTM types I, III, VII and IV special packaging for fluoride products are technically feasible, practicable, and appropriate. To achieve senior friendly CRP it may be necessary sometimes to use a different ASTM type special packaging.

CONTINUOUS THREADED (ASTM I), SNAP (ASTM III) RECLOSABLE AND TRIGGER SPRAYER (ASTM IX) DISPENSER CR PACKAGING:

There are regulated PPPA products on the market with ASTM type I, III, and IX, CRP that comply with SAUE requirements. Supplies of senior friendly CRP are available.

AEROSOL (ASTM VIII) MULTIPLE APPLICATION CR PACKAGING:

A senior friendly overcap is being used by one product manufacturer. CR overcap manufacturers have indicated, with adequate time, they can make available suitable commercial special packaging. In this case, additional time is required for CR overcap companies to implement new sizes, redesign, obtain molds, protocol test, and start commercial production. Nine months to one year is needed to insure adequate supplies of new senior friendly and child resistant special packaging.

The same findings relating to technical feasibility, practicability, and appropriateness can be made for the fluoride exemption as for the final rule for fluoride containing products.

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11. Tewabe, A., Wilbur, C., Laboratory Report, Form 221, Non-CR Mechanical Pump Trigger Sprayer Dispenser with Non-CR Screw Cap attachment to a 18 oz. Plastic Handled Bottle, 97-594-0289, No. 2929, CPSC, Health Sciences, May 30, 1997.

12. Tewabe, A., Wilbur, C., Laboratory Report, Form 221, ASTM IX B (1) CR Mechanical Pump Trigger Sprayer Dispenser with CR Screw Cap attachment to a 17 oz. Plastic Handled Bottle, 97-594-0291, No. 2928, CPSC, Health Sciences, June 9, 1997.

13. Tewabe, A., Wilbur, C., CR Mechanical Pump Trigger Sprayer Dispenser, ASTM IX B (1), with CR Screw Cap attachment to a 17 oz. Plastic Handled Bottle, Laboratory Report, Form 221, CPSC, Health Sciences, 97-594-0291, No. 2928, June 9, 1997, and Child/Senior Protocol Test Data, October 15, 1997.

14. Child Resistant Packaging Mechanical Finger Pump Dispenser Manufacturer, Confidential Communication, CPSC Form, 247, March 11, 1998.

TAB G

Draft 5/4/98 Billing Code 6355-01

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 _____, 1998 [insert date that is 9 months after publication in the FEDERAL REGISTER], 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]

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[1] The percentage of elemental fluoride in any compound is determined by dividing the molecular weight of fluoride (~ 19 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 x 100 = 45%).

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

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 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 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

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[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.

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.141 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, generaily, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either tc 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 in-jury 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)(l). 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: 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 to revise paragraph (a) (10) (vii) and to add paragraph (a)(27) to read as follows (although unchanged, the introductory text of paragraphs (a) and (10) are included 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 meeting the requirements of § 1700.20(a) is required tc 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-vciume basis for liquids or a weight-to-weight basis for ncn-liquids shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c).

Dated: _____

_____
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, 1.997.

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," April , 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, 199'7.

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, 1.991.