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 71 as follows:

PART 71—[AMENDED]

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

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

§ 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 Tracy 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 Tracy 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 11–19–97; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Household Products With 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: 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 under 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 20814–4408, 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 bifluoride, ammonium fluoride, potassium bifluoride, sodium bifluoride, 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 weight of the compound (e.g., the molecular weight of sodium fluoride = 42 grams/mole). Sodium fluoride contains 45% elemental fluoride (19/42 × 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, 0.5–1 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 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). 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 50 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 burns. 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 GI symptoms. Reports suggest that ingesting 3 to 5 milligrams per kilogram of fluoride 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 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 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. 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 bifluoride). 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.[2]

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 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 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 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]

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 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 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]

D. Level of Regulation for Household Products Containing Fluoride

The Commission is proposing 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 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 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 certainly lethal 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 burns. [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 level for the oral prescription drug exemption be changed to allow no more than the equivalent 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 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. 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]

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 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]

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-friendly special packaging is currently commercially available for most types of CR packaging. Aerosol and mechanical pump packages should be commercially available in senior-friendly 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 1-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 cleaners, 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 1021.5(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)(1). In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the 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 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 to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

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

* * * * *

(vii) Sodium fluoride drug preparations including liquid and tablet forms, containing not more than 110 milligrams of sodium fluoride (the equivalent of 50 mg of elemental fluoride) per package 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 50 milligrams of elemental fluoride per package and more than the equivalent of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids shall be packaged in accordance with the provisions of § 1700.15 (a), (b) and (c).

Dated: November 17, 1997.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

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

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

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

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

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

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 240 and 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 govern 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