§ 91.3 [Amended]

2. Section 91.3 is amended as follows:

a. In paragraph (a), in the first and second sentences, the words ''by land'' are added immediately before the phrase ''to Mexico or Canada''.

b. In paragraph (b), in the first and second sentences, the words ''by land'' are added immediately before the phrase ''to Mexico or Canada''.

c. At the end of the section, in the parenthetical statement, ''0579–0069'' is removed and ''0579–0020'' is added in its place.

§ 91.5 [Amended]

3. In § 91.5, at the end of the section, in the parenthetical statement, ''0579-0069'' is removed and ''0579-0020'' is added in its place.

§ 91.6 [Amended]

4. In § 91.6, at the end of the section, in the parenthetical statement, ''0579–0069'' is removed and ''0579–0020'' is added in its place.

§ 91.14 [Amended]

5. In § 91.14, paragraph (a), introductory text, in the second sentence, the words ''by land'' are added immediately before the phrase ''to Mexico or Canada''.

§ 91.15 [Amended]

6. In § 91.15, in paragraph (a), the words ''by land to'' are added immediately before the phrase ''Mexico or Canada''.

Done in Washington, DC, this 18th day of January 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–1740 Filed 1–23–95; 8:45 am]

BILLING CODE 3410–34–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Mouthwash Packages Containing 3 Grams or More of Ethanol

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Under the Poison Prevention Packaging Act of 1970, the Commission is issuing a rule to require child-resistant packaging for mouthwashes with 3 grams or more of absolute ethanol per package. The Commission has determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from ingesting mouthwash. The rule exempts mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single package available to the consumer.

DATES: The effective date of the rule is July 24, 1995, and the rule shall apply to products packaged on or after that date.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400 ext. 1368.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutes and Regulations

The Poison Prevention Packaging Act of 1970 (the ''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 packaging,'' is defined as packaging that 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. (It does not mean, however, packaging which all such children cannot open, or obtain a toxic or harmful amount from, within a reasonable time.)

Under the PPPA, standards have been established for special packaging (16 CFR 1700.15), as has a test procedure for evaluating its effectiveness (16 CFR 1700.20). Regulations requiring special packaging for a number of household products are published at 16 CFR 1700.14. The statutory findings that the Commission must make in order to issue a standard requiring child-resistant (''CR'') packaging (''CRP'') for a product are discussed below in Section D of this notice.

The PPPA allows the Commission to require CRP for household substances, which include (among other specified 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). Mouthwashes are either drugs, if they make medical claims, or cosmetics.

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-CRP only if (1) the manufacturer (or packer) also supplies the substance in CRP and (2) the non-CRP bears conspicuous labeling stating: ''This package for households without young children.'' 15 U.S.C. 1473(a). If the package is too small to accommodate this label statement, the package may bear a label stating: ''Package not child-resistant.'' 16 CFR 1700.5(b). The right of the manufacturer or packer to market a single size of the product in noncomplying packaging under these conditions is termed the ''single-size exemption.''

The Commission may restrict the right to market a single size in noncomplying packaging if the Commission finds that the substance is not also being supplied in popular size packages that comply with the standard. 15 U.S.C. 1473(c). In such cases, the Commission may, after giving the manufacturer or packer an opportunity to comply with the purposes of the PPPA and an opportunity for a hearing, order that the substance be packaged exclusively in CRP. To issue such an order, the Commission must find that the exclusive use of special packaging is necessary to accomplish the purposes of the PPPA.

2. The Mouthwash Petition

On March 2, 1993, the Commission was petitioned to require CRP for mouthwashes containing more than 5% ethanol. The petition was submitted by the American Academy of Pediatrics, the American Association of Poison Control Centers, the Center for Science in the Public Interest, and 28 states, Guam, and the Northern Mariana Islands. For the purposes of this proceeding and the final rule, the term ''mouthwash'' includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

The petitioners stated several reasons for their request: (1) Many mouthwashes

contain high percentages of ethanol, an extremely toxic substance, in a package large enough to cause children serious injury or death; (2) these mouthwashes are accessible to children because they are generally considered innocuous and do not have CRP; (3) they are attractive to children because of their appealing taste, color, and smell; and (4) data show that children have been seriously injured or died from accidental ingestion of ethanol-containing mouthwashes.

By a letter dated June 3, 1993, the Nonprescription Drug Manufacturers Association (''NDMA'') and the Cosmetic, Toiletry, and Fragrance Association (''CTFA'') advised Commission staff of the associations' plans to implement a voluntary program to place mouthwashes with more than 5% ethanol in CR containers. [1, Tab C.][1] On November 17, 1993, the Commission granted the petition. Subsequently, in April 1994, the NDMA and CTFA notified the Commission that the products subject to their voluntary program had been changed from mouthwashes with more than 5% ethanol to mouthwashes with 3 grams or more in a single container.

3. The Proposed Regulation

The mouthwash petition requested that the Commission require CRP for mouthwash that contains more than 5% ethanol. However, after analyzing the information before it, the Commission decided to propose that mouthwash products with 3 grams (g) or more of absolute ethanol per package or retail-sale unit should be subject to the regulation. [10] This level is obtained by dividing the lethal dose of ethanol (3 g/kg of body weight) for a 10-kg child (30 g) by a safety factor of 10. This safety factor is needed because less than the ''lethal'' dose can produce serious toxic effects, or even death from hypoglycemia or other secondary effects.

Three grams of absolute ethanol are present in a small amount (approximately 2.6 ounces) of mouthwash with 5% ethanol. The Commission is concerned that regulating only products with more than 5% ethanol, as requested in the petition, might not sufficiently protect children because the quantity of ethanol available to be consumed is more relevant to the safety issue than is the concentration of ethanol in a mouthwash. Accordingly, the Commission proposed a regulatory threshold of 3 g total ethanol in the package rather than the concentration of 5% or more of ethanol in the product.

The proposed rule was published for public comment on May 11, 1994. 59 FR 24386.

B. Toxicity

[2, unless noted otherwise.] The Commission's toxicity review indicates that mouthwashes with ethanol can present a serious ingestion hazard to children. Most of the popular adult mouthwashes contain between 14% and 27% ethanol. By comparison, beer contains between 5% and 7% ethanol and wine can contain 12% to 14% ethanol.

Ethanol depresses the central nervous system. Symptoms of acute ethanol poisoning in children include irritability, lethargy, and unconsciousness which can lead to coma and death at high doses. Lethal blood levels of ethanol in children are reported to range between 250 and 500 mg/dl, and the lethal dose of ethanol is 3 g/kg. Deaths or serious injury may occur at lower doses due to other ethanol-induced effects. Ethanol poisoning in children can produce certain metabolic complications, such as hypoglycemia, metabolic acidosis, and hypokalemia.

A review of the relevant literature shows that three deaths of children under 5 years of age have been reported. The most recent death reported occurred in 1992 and involved a 3-year-old girl who ingested an unknown amount of mouthwash that contained 18% ethanol. Several other cases of ethanol-induced hypoglycemia or toxicity following mouthwash ingestion are reported in the literature.

The National Electronic Injury Surveillance System (''NEISS'') reported 40 mouthwash cases involving children under age 5 from January 1987 through July 1994. [14] Based on these ingestions, it was estimated that a total of 1,840 mouthwash poisoning cases were treated in hospital emergency rooms in the United States during that time, or an average of about 240 per year. [14]

In addition to these sources, the American Association of Poison Control Centers' National Data Collection System (''AAPCC'') includes cases reported by participating poison control centers. The AAPCC reported 1,966 ingestions of mouthwash with ethanol by children under 5 years old in 1992. [14] Of these ingestions, 182 were referred to a health care facility by the poison control center. Another 64 cases either were already in a health care facility or were on the way to one when the poison control center was contacted.

C. Comments on the Proposal

The Commission received nine comments in response to the proposed rule. [13] The New York State Consumer Protection Board, the American Dental Association, and several students from Florida International University expressed strong support for the rule. The university students also submitted the results of an informal survey of mouthwash use.

The NDMA/CTFA Joint Oral Care Task Group and several industry members also favor the proposed rule. However, these and other commenters disagreed with the proposed effective date, and questions were raised about the application of the rule. The issues raised by the comments are discussed below.

Exemption for Certain Pump Dispensers

The manufacturer of one product that otherwise would have been subject to the proposed rule requested an exemption. [15] This product is an oral rinse concentrate marketed in a 2-oz (59 ml) glass bottle containing 24% ethanol by weight, for a total of 14.16 g of ethanol per package. This product utilizes a screw-on metered pump to dispense the product, and has a protective overcap. The use instructions call for five actuations of the pump (for a total of 0.6 ml, or less than 0.025 oz) into a small cup supplied with the product. This amount is then diluted with up to 1 oz of water for use. The Commission is unaware of any other manufacturer of a product subject to the rule that uses this type of package.

In 1987, one ingestion of a mouthwash made by this manufacturer was reported in the NEISS database. The child involved in that incident was treated and released. However, it cannot be determined from the report whether this incident involved the concentrated spray product or another, non-concentrated mouthwash that may have been available from that manufacturer at that time.

Human experience data submitted by the manufacturer show that from January 1990 to September 1994 there were 117 known cases of accidental ingestion of this product by children under 5 years old. [15] All cases resulted in either no effects or only minor ones. All but one of these cases were treated at home. In that one case, the child was taken to a health care facility at the insistence of the parents. These cases all involve product packaged in the current screw-on pump dispenser.

[1] Numbers in brackets refer to the number of a document as listed in App. 1 at the end of this notice.

The case reports indicate that 102 of the children (87%) gained access to the product by unscrewing the top of the bottle. None of the reports indicated that the child gained access to the product by using the pump, but 12 reports did not specify the way in which the child accessed the product.

If the product were marketed in a nonremovable pump, which the manufacturer has stated it intends to do in July 1995, the only way a child could access a regulated amount of the mouthwash concentrate would be to spray the product at least 100 times into the mouth and swallow the sprayed product. One study shows that many children physically could activate the pump this many times. However, the study did not note that any of the children sprayed the contents of the package (in this test, water) into their mouths. If they had, it likely would have been documented in the study.

Since this product is intended to be used in a diluted form, the packaged form contains a very high concentration of flavoring oils. The CPSC staff examined this aspect and concluded that the irritant properties of this concentrated flavoring would create unpleasant or painful sensations. [18] CPSC's Human Factors staff have concluded that it is highly unlikely that children would ingest a significant quantity of the product by means of repeated sprays. [18]

Based upon all of the above information, the Commission has decided that this rule should not apply to mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single unit.

Effective Date

The proposed rule specified that the rule should become effective on May 1, 1995, or 6 months after the rule is published in the **Federal Register**, whichever is earlier. A number of comments were received opposing an effective date any earlier than May 1, 1995. This issue is now moot, since May 1, 1995, is now the earlier of the two dates. The time needed to analyze issues concerning the requested exemption and how the effective date should apply to special situations, described below, prevented earlier publication of the final rule.

Manufacturers that claim to be responsible for over 95% of the production of ethanol-containing mouthwash are committed to be in compliance by May 1, 1995. This commitment, however, was based on there being no change in the Commission's PPPA test protocol. [8] However, the Commission has proposed to modify the test protocol by which CRP is evaluated in order to make the packaging easier for adults to open (referred to as ''senior-friendly'' packaging). 59 FR 13264 (March 21, 1994). Accordingly, the Commission's staff contacted five companies that will be subject to the rule for mouthwash containing ethanol to see how the possibility that the PPPA protocol may be amended to require senior-friendly packaging would affect these companies. [20]

Three of the companies contacted belong to the groups that are sponsoring the implementation of voluntary CRP for mouthwash containing ethanol by May 1, 1995. These three companies expect to have their products in packaging that meets the present protocol by that date.

One of the other companies contacted originally had intended to comply with the rule by reducing its ethanol concentration below the greater-than-5-percent level specified in the first version of the voluntary program and in the petition to the Commission. When the Commission proposed to regulate 3 grams or more in a single package, this manufacturer was no longer able to comply by reducing its ethanol content. Thus, this manufacturer had a late start in converting to CRP. This manufacturer now estimates that it may have CRP by July 1995. [21]

The remaining manufacturer contacted recently by the staff is a small company that estimates it will not be ready with a package that would satisfy either the current protocol or the proposed senior-friendly protocol until December 1995. The company states that this length of time is required because it must change its bottle molds, in addition to its capping equipment, in order to accept either current or senior-friendly CRP.

All five of these companies are aware of the proposed senior-friendly protocol. None of these companies anticipates major problems from a subsequent regulation requiring CRP to be senior-friendly. Of these manufacturers, one is already marketing its product in senior-friendly packaging, which it is purchasing from a supplier. Three others intend to purchase commercially available CRP. One of these intends to begin production by May 1, 1995. The other two of these manufacturers intend to have senior-friendly packaging in production by July 1995 and December 1995, respectively. The fifth contacted manufacturer is developing packages that it intends to ultimately be senior-friendly. This manufacturer intends to have the new package in production by May 1, 1995. That manufacturer states that, if its design is not senior-friendly initially, it can be modified to be so.

None of the manufacturers contacted stated that it would have to design an additional package if there are changes to the CRP protocol. The manufacturers contacted, together with another manufacturer known to be marketing its mouthwash in senior-friendly CRP, represent an estimated 70 percent of mouthwash sales. Thus, it appears that the possibility of changes to the test protocol to ensure that CRP is senior-friendly is not a significant factor in the choice of effective date for the CRP standard for mouthwash containing ethanol.

The Commission has learned of a few small manufacturers of concentrated mouthwash products, marketed in bottles with continuous-threaded (CT) caps. One of these manufacturers filed a late comment on the proposed rule. [13, No. CP94–2–9] That commenter's product contains 70% ethanol and is marketed in 2-, 4-, 8- and 16-oz sizes. The other manufacturers' products are believed to also have high ethanol concentrations. The commenter expressed concern about the proposed May 1, 1995, effective date, but did not expressly ask for a later date or say how long it would take to convert to CRP.

Some of the bottles used by these manufacturers can use existing CR or senior-friendly CR caps without modification; others will require a long-skirted cap, e.g., a 415 finish, to fit their existing bottles. [17] For the manufacturers needing a long-skirted cap, a major CRP manufacturer has said that senior-friendly caps in 20mm, 24mm, and 28mm sizes with a long-skirt special 415 finish have been commercially available since October 1994. [17] For those manufacturers that have to change caps, the capping equipment will need to be modified to account for the larger diameter of the CR cap. This is not a complicated or expensive modification. [17]

The only known manufacturer of the oral rinse concentrate that will be exempt from the rule if marketed in a nonremovable pump has indicated that it will switch to a crimped-on nonremovable pump in July 1995. [Telephone conversation, September 8, 1994.]

After considering the currently available information, the Commission concludes that an effective date of [insert date that is 6 months after

publication], which is 6 months after publication of the final rule, is reasonable. The vast majority of manufacturers are committed to being in compliance before this, by May 1, 1995. The one company that states it needs until December 1995 to comply may be able to do so much sooner. Moreover, this company may have sufficient inventory to cover the period of time between the effective date and the date complying packaging can be provided. Furthermore, revenue from mouthwash does not constitute the major portion of its sales.

For the instances where modifications to the bottles or development of special caps for these bottles are required, the manufacturers may not be able to incorporate them into production by July 24, 1995. In this event, these manufacturers may have to use other bottle/cap combinations from contract packagers until other arrangements can be made.

Applicability of the Effective Date

In the proposal, the effective date would apply to products packaged after the effective date. A commenter requests that the effective date should apply to products shipped on or after that date. The commenter's request that the effective date should apply to the shipping date would tend to reduce any potential motivation for stockpiling noncomplying product packaged before the effective date. This request cannot be granted, however, because PPPA § 8, 15 U.S.C. 1471n, mandates ''[n]o [special packaging] standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.''

Definition of ''Single Retail Unit''

The proposal specified that the rule applied to products containing 3 g or more in a single package. The proposal explained that the ''single package'' to be covered by the rule was a ''single retail unit.'' A commenter stated that the term ''single retail unit'' should be defined as ''a package intended to be made available to consumers for direct retail purchase.''

The use of the term ''single retail unit'' was intended to clarify that a regulated substance supplied in a retail package which contained smaller packages that, considered individually, would not be subject to the rule because each of the smaller packages contained less than the regulated amount, would be subject to the CRP standard if the total amount of the regulated substance in the retail package exceeded the regulated amount. The proposal did not intend to limit the applicability of the standard to packages sold at retail.

In view of this comment, the Commission concludes that the term ''single retail unit'' is confusing in this context. Rather, the Commission considers the term ''package'' to mean the container or wrapping in which a household substance is supplied for consumption, use, or storage by individuals in or about the household. This includes, but is not limited to, any package intended to be made available to consumers for retail purchase. This definition is not intended to be the same as the statutory definition of ''packaging'' at PPPA § 2(3), 15 U.S.C. 1471(3).

Definition of ''Household Substance''

A commenter contended that ''amenities'' do not fall within the definition of ''household substance'' in 15 U.S.C. 1471(2). Amenities are small quantities of substances, such as soap, shampoo, or mouthwash, that are placed in hotel rooms or other accommodations for use by the room's occupants. If the commenter's contention were correct, amenities would not be subject to an otherwise applicable PPPA standard.

The PPPA's definition of household substance includes ''any substance which is customarily produced or distributed for sale for consumption or use * * * by individuals in or about the household and which is * * * a hazardous substance as [defined in the Federal Hazardous Substances Act (''FHSA'')] * * * [or] a food, drug, or cosmetic [as defined in the Federal Food, Drug, & Cosmetic Act].'' PPPA § 2(2), 15 U.S.C. 1471(2). Mouthwash subject to the proposed rule clearly is either a hazardous substance or a drug or cosmetic. How the other elements of this definition apply to mouthwash distributed as amenities in hotel rooms is discussed below.

1. Mouthwash amenities are ''sold'' for use by individuals. If a hotel purchases prepackaged units of mouthwash to place in hotel rooms, such packages clearly are sold to the hotel for use by individuals. In the unlikely event that hotel employees repackage mouthwash from a larger container to a smaller one to be left in the room, the mouthwash is nevertheless sold to the hotel for use by individuals since only individuals can use mouthwash. In addition, the mouthwash amenity can be viewed as being sold to the hotel occupants, since the amount paid by the hotel guests for lodging also pays for providing the mouthwash.

2. Items used in hotel rooms are used ''in or about the household.'' One definition of the term household is ''the home and its affairs.'' ''Home'' in turn is defined as ''the house, apartment, etc., where one lives or is living temporarily; living quarters.'' Webster's New World Dictionary. Hotels and other places that provide amenities are places where people live, however temporarily. Therefore, hotels are households.

Another definition of household is ''those who dwell under the same roof and compose a family: A domestic establishment; specif: A social unit comprised of those living together in the same dwelling.'' Webster's Third New International Dictionary of the English Language Unabridged, 1986 Ed. (''Webster's Unabridged''). Thus, under this definition, a household refers to a group of people rather than to any particular type of building. Accordingly, if a hotel rents rooms where more than one member of a household may stay at a time, amenities used in those rooms are used ''in or about the household.''

The Commission's regulations under the FHSA state that an ''article is suitable for use in or around the household * * * [if] under any reasonably foreseeable condition of purchase, storage or use the article may be found in or around a dwelling.'' 16 C.F.R. 1500.3(c)(10)(i). The term ''dwelling'' means ''a building or construction used for residence: ABODE, HABITATION.'' *Webster's Unabridged*. This term is not limited to a permanent home or primary residence. Thus, the Commission's rules lend support to the interpretation that items used in hotels are used ''in or about the household.''

Finally, even if a hotel room were not a household, it is customary, and expected, that amenities will be removed from hotel rooms by guests for use at home. Thus, for this independent reason, amenities are ''customarily produced or distributed for sale for consumption or use * * * in or about the household.''

For the reasons given above, the Commission concludes that amenities supplied in hotel rooms and the like are household substances, as that term is used in the PPPA.

D. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning children's ingestion of ethanol-containing mouthwash demonstrate that the amount of ethanol in available mouthwash preparations is sufficient to cause serious illness and injury to children. These mouthwash preparations are readily available to children. Even though the

manufacturers of these mouthwashes that are members of the NDMA and CFTA will voluntarily use CRP for their products, the Commission concludes that a regulation is needed to ensure that mouthwash will be placed in CRP by all mouthwash packagers. In addition, the regulation will enable the Commission to enforce the CRP requirement and ensure that effective CRP is used.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that the degree and nature of the hazard to children from ingesting ethanol-containing mouthwashes is such that special packaging is required to protect children from serious illness. The Commission bases this finding on the toxic nature of such mouthwashes, described above, the accessibility of such preparations to children in the home, and the existing incident data involving ingestions by young children.

2. Technical Feasibility, Practicability, and Appropriateness

[17] In issuing a standard for special packaging under the PPPA, the Commission is required by section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), to find that the special packaging is ''technically feasible, practicable, and appropriate.'' Technical feasibility exists when technology exists 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. Appropriateness exists when packaging complying with the standards will adequately protect the integrity of the substance and not interfere with the intended storage or use.

CRP are mass produced for products that contain ethanol and have similar properties to mouthwashes. Two industry groups have indicated that their members would have CRP for one size of their mouthwashes by August 31, 1994, with their entire lines converted by May 1, 1995. In addition, one major manufacturer of mouthwash has introduced a popular size of its product in packaging that is not only child resistant, but is easier for adult consumers (and especially older adults) to open. Therefore, the Commission concludes that CRP for mouthwashes is technically feasible, practicable, and appropriate.

3. Other Considerations

In establishing a special packaging standard, section 3(b) of the PPPA, 15 U.S.C. 1472(b), requires the Commission to 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).

These items have been considered with respect to the various determinations made in this notice, and the Commission finds no basis for concluding that the rule is unreasonable.

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, 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.

As discussed above in Section C of this notice, the Commission has established the effective date for this rule as July 24, 1995, which is 6 months after publication of the final rule.

F. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* generally requires the agency to prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. The purpose of the Regulatory Flexibility Act, as stated in section 2(b) (5 U.S.C. 602 note), is to require agencies, consistent with their objectives, to fit the requirements of regulations to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulations. 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 Economics prepared an economic assessment of this rule to require special packaging for mouthwash preparations with 3 g or more of ethanol in a single package. [16] Based on this assessment, the Commission concludes that such a requirement would not have a significant impact on a substantial number of small businesses or other small entities because of the widespread acceptance of the voluntary CRP program. CRP for mouthwash preparations is readily available at a relatively low incremental cost, and the PPPA permits manufacturers to market preparations in one non-CR size. The relatively low costs of CRP should not be a burden to current small business manufacturers or an entry burden for future marketers. Manufacturers are given enough time to use up existing supplies of non-CRP and to obtain suitable CRP and incorporate its use into their packaging lines.

Individual firms and associations representing businesses affected by the proposed rule commented that impacts would not be significant as long as the effective date was no sooner than May 1, 1995, and there was no change in the PPPA test protocol. That date was originally proposed by the industry trade association in a voluntary program to provide CRP for mouthwash; the date was based on the length of time determined by the members to be reasonable and workable. Many commenters advised the Commission that an effective date of May 1, 1995, would allow sufficient time to complete package development, modify equipment, conduct protocol and stability testing, and implement marketing programs.

The Commission has decided to exempt from this regulation mouthwash products using nonremovable pumps that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 g of absolute ethanol per pump actuation, and that contain less than 15 g of ethanol in a single unit. This will potentially reduce the adverse impacts of the rule. However, the only known manufacturer of a product that would qualify for the exemption, except that its current pump is removable, is not a small entity. [Manufacturing USA, 2nd Ed. (1992), Gale Research, Detroit, p. 677.]

Based on a comment to the proposal, the Commission has learned that there are about four or five small businesses that market mouthwash products that will need CRP. If these marketers do not reformulate to eliminate ethanol from their products, they may incur incremental costs for CRP, compared to the non-CRP now used. They may also incur costs to modify equipment to accommodate new packaging components. However, these costs are not expected to be high. In any event, the Commission could grant a temporary enforcement exemption to companies—in this case, most likely only a few small companies—who demonstrate that, despite reasonable efforts, they are unable to meet the effective date.

Accordingly, for the reasons given above, the Commission concludes that the number of small entities that market products subject to the rule requiring special packaging for mouthwashes containing 3 g or more of ethanol is not substantial. Also, the economic effects on such firms will not be significant.

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the Poison Prevention Packaging Act (PPPA) packaging requirements for ethanol-containing products. [4]

The Commission's regulations at 16 CFR 1021.5(c)(3) state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Analysis of the impact of this rule indicates that CRP for these mouthwash preparations will have no significant effects on the environment. This is because the rule will not significantly increase the total amount of CRP in use and, in any event, the manufacture, use, and disposal of CRP presents the same environmental effects as do the currently used non-CRP.

Therefore, because the rule will have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission 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 by adding new paragraph (a)(22), reading as follows (although unchanged, the introductory text of paragraph (a) is 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 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:

* * * * *

(22) *Mouthwash.* Except as provided in the following sentence, mouthwash preparations for human use and containing 3 g or more of ethanol in a single package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c). Mouthwash products with nonremovable pump dispensers that contain at least 7% on a weight-to-weight basis of mint or cinnamon flavoring oils, that dispense no more than 0.03 grams of absolute ethanol per pump actuation, and that contain less than 15 grams of ethanol in a single unit are exempt from this requirement. The term ''mouthwash'' includes liquid products that are variously called mouthwashes, mouthrinses, oral antiseptics, gargles, fluoride rinses, anti-plaque rinses, and breath fresheners. It does not include throat sprays or aerosol breath fresheners.

* * * * *

Dated: January 18, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

(**Note.** This list of relevant documents will not be printed in the Code of Federal Regulations.)

1. Briefing Memorandum with attached briefing package, September 30, 1993.

2. Memorandum from Jacqueline Ferrante, Ph.D., HSPS, to James F. Hoebel, Acting Associate Executive Director for Health Sciences, ''Recommendation for the level of regulation of mouthwash with ethanol,'' January 10, 1994.

3. Memorandum from Terry Kissinger, Ph.D., EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Injury Data Related to the Toxicity of Ethanol-containing Mouthwash,'' January 31, 1994.

4. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Preliminary Assessment of Economic and Environmental Effects of a Proposal to Require Child-Resistant Packaging for Mouthwash Containing Ethanol,'' February 24, 1994.

5. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Proposal to Require CRP for Mouthwash Preparations Containing Ethanol,'' February 24, 1994.

6. Memorandum from Marcia P. Robins, ECSS, to Ronald L. Medford, EXHR, ''Economic Effects of an Earlier Effective Date for CR Packaging of Mouthwash Preparations Containing Ethanol,'' April 6, 1994.

7. Briefing memorandum from Jacqueline N. Ferrante, Ph.D., HSPS, to the Commission, ''Proposed Special Packaging Standard for Mouthwash Products with Ethanol,'' with Tabs A–E, April 11, 1994.

8. NDMA/CTFA Joint Voluntary Program on Child Resistant Packaging for Alcohol Containing Mouthwashes (Revised).

9. Memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Revised industry voluntary program for child-resistant packaging of mouthwashes with ethanol,'' April 21, 1994.

10. Memorandum from Harleigh Ewell, GCRA, to the Commission, transmitting a revised **Federal Register** notice, April 21, 1994.

11. Letter from Eric A. Rubel, CPSC General Counsel, to Ms. Doris S. Freedman, Acting Chief Counsel for Advocacy, Small Business Administration, transmitting Regulatory Flexibility Act finding, May 4, 1994.

12. Proposed rule, 59 FR 24386 (May 11, 1994).

13. Public comments on proposed rule, Nos. CP94–2–1 through CP94–2–9.

14. Memorandum from Dr. Terry Kissinger, EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Update of injury Data Related to the Toxicity of Ethanol-Containing Mouthwash,'' September 1, 1994.

15. Letter from David J. Aupperlee, Amway Corporation, to Jacqueline Ferrante, Ph.D., requesting an exemption for Amway Glister Anti-Plaque Oral Rinse [contains some claimed confidential information], October 19, 1994.

16. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Final Regulatory Flexibility Analysis: Child-Resistant Packaging for Mouthwash Containing Ethanol,'' October 27, 1994.

17. Memorandum from Charles Wilbur, HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Child-Resistant Packaging for Mouthwash Preparations Containing Ethanol,'' November 1, 1994.

18. Memorandum from Catherine A. Sedney, EPHF, to Jacqueline Ferrante, Ph.D., HSPS, ''Request for Exemption from Requirements for Special Packaging for Mouthwash,'' November 17, 1994.

19. Briefing paper from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, with Tabs A–G, November 29, 1994.

20. Memorandum from Jacqueline Ferrante, Ph.D., to the Commission, ''Supplemental information concerning a PPPA requirement for mouthwash with ethanol,'' December 12, 1994.

21. Letter from George Andrassy, Dep Corporation, to Sadye Dunn, Secretary of the CPSC, November 14, 1994.

[FR Doc. 95–1691 Filed 1–23–95; 8:45 am]

BILLING CODE 6355–01–P