# §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

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 childresistant 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-toweight 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 childresistant ("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