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 ethanolcontaining 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

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-toweight 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.