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 longskirted 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