

a tool-assisted opening feature can ensure child-resistance. However, making this cap senior-friendly is more difficult.

The Commission concludes that the available information support the finding that senior-friendly mechanical pump packaging is technically feasible.

D. Practicability

For ASTM types I, II, III, IV and VIII, (CT, lug, snap, pouch, blister, and mechanical dispensers) senior-friendly CRP are presently being used by some companies for regulated products. [232, 240] These companies use assembly line and mass production techniques in their manufacturing processes. This shows that it is practicable to package regulated products in special packaging. No major problems are anticipated in this change from the manufacturing standpoint.

Two CRP manufacturers state that ASTM types VII (hinged overcap) and IX (mechanical pump, with a CR overcap) senior-friendly special packaging can be made commercially available and are practicable. [232] This is supported by one manufacturer that supplies its CR overcap commercially. [232, Ref. 16] Modifications would need to be made to the assembly line to include the CR overcap feature, and production techniques may require modifications to obtain a satisfactory manufacturing process. This special package can be implemented into a product manufacturer's assembly line and production manufacturing process. Therefore, it is practicable to package products in aerosol and mechanical pump special packaging with overcaps.

Also, the Commission is aware of an aerosol design that can be actuated by an adult-sized finger but not by a child's. [216, 240 Ref. 12] Like the CR overcap design, this package can be used with assembly line and mass production techniques and is therefore practicable. For the reasons discussed above, however, products that must be packaged in aerosol form or in metal cans are not required to meet the senior-friendly requirements in the rule.

E. Appropriateness for the Substance

Some companies are presently using senior-friendly ASTM types I, II, III, IV and VIII special packaging for their products. Companies can use existing CRP designs and materials that have proven not to be detrimental to the integrity of the substance and have not interfered with its storage or use. The implementation of senior-friendly packaging should not affect shelf-life and integrity, because it is anticipated that the same packaging materials could

be used in contact with the product. FDA or DOT approval may be required if a switch in packaging is required for a particular product. However, the record information supports the finding that senior-friendly CRP of ASTM types I, II, III, IV, and VIII are appropriate for the packaged substances.

Available information also supports the finding that senior-friendly CRP of ASTM types VII and IX is appropriate for the packaged substances. The CR overcap method of packaging has successfully been used. [232] The CR overcap concept does not affect the integrity of the substance or interfere with its storage or use, because the CR overcap is separate from the product container. Product shelf-life and integrity would not be expected to change, as it is anticipated that the same packaging materials could be used in contact with the product.

F. Conclusion

The Commission concludes that the revised protocols will ensure that special packaging will be significantly difficult for children under age 5 to open or obtain a toxic or harmful amount of the contents within a reasonable time and will not be difficult for normal adults to use properly. The Commission also finds that for the products covered by the revised rule, special packaging is technically feasible, practicable, and appropriate for the substances.

VI. Effective Date

Section 8 of the PPPA, 15 U.S.C. 1471n, requires that the effective date of a special packaging standard "shall not be sooner than one hundred and eighty days or later than one year from the date such regulation is final, unless the [Commission], for good cause found, determines that an earlier effective date is in the public interest and publishes in the **Federal Register** [the] reason for such finding, in which case such earlier date shall apply." As explained below, the Commission is establishing different effective dates for some of the amendments being issued.

With regard to the revised requirements for the senior-adult test panel, senior-adult test times, and standardized senior-adult instructions, there are regulated PPPA products on the market with ASTM type IA, IB, IIA, IIIA, IVA, IVC, VIID, and VIIIE CRP that comply with the SAUE requirements. This is demonstrated by CPSC and ASTM/ISR senior-adult protocol test results.

Most PPPA-regulated substances could be packaged in senior-friendly CRP in 1 year. [232, 240] Additional

time may be required for others. To serve the market, over 3 billion senior-friendly CRP need to be manufactured per year. The CRP design modifications, mold changes, protocol testing, and, in some cases, FDA stability or DOT performance testing all require time to complete before commercial production of senior-friendly CRP can begin.

Companies that currently make senior-friendly CRP do not presently have the production capacity to meet the entire demand.

Two CR overcap manufacturers have indicated that, with adequate time, they can make suitable ASTM type VII and IX senior-friendly CR overcaps. [232, Refs. 15 and 16] This type of CR feature can be used with packaging using mechanical pumps. Additional time may be required for the two CR overcap manufacturing companies to redesign for new sizes, obtain molds, protocol test, and start commercial production. More than 1 year may be needed to ensure adequate supplies of new senior-friendly and CR packaging.

Therefore, the Commission is allowing the maximum time permitted by statute, 1 year, as the effective date for the senior-adult test panel, senior-adult test times, senior-adult standardized instructions, and limitations on sites and testers for the younger-adult test. The Commission is also granting an 18-month blanket exemption from compliance after the effective date in order to ease the burden on industry. In addition, the Commission is implementing a procedure whereby companies unable to comply within that time, despite their good-faith efforts to do so, may apply for temporary enforcement stays. These temporary enforcement stays are described in section III(I) of this notice, concerning the Commission's response to comments on the effective date.

The child-test amendments concerning sequential testing, three age groups, standardized instructions, and the limitations on sites and testers are not expected to change the results of these tests. However, to allow time for companies to complete ongoing studies and plan future studies, these amendments will become effective January 24, 1996.

The amendments to publish the suggested guidelines for an appropriate resecuring test will become effective August 21, 1995. The Commission finds that this effective date is in the public interest because the guidelines provide additional options for achieving reliable test results, yet, since they are not mandatory, do not impose new obligations on companies. Therefore,