protocol), to use standard (supplier stocked, on-the-shelf) SAUE packaging, or to reformulate or withdraw a product. Some SAUE packaging is available now; other SAUE package types, including those for products having formulations that impose unusual requirements on packaging, are expected to become available. Changes in packaging may require associated equipment purchases or modifications. Costs of testing some products to meet the requirements of government agencies other than CPSC may be required if packaging is changed. Incremental costs associated with new SAUE packaging should not add materially to the costs of a product and are expected to be passed on to the consumer.

CPSC does not anticipate that any substantial number of small businesses will be significantly affected, however, because of the current and expected future availability of SAUE packaging for all types of product formulations. If necessary, companies can apply for a temporary stay of enforcement to comply with the rule.

D. Pharmaceutical Packagers

There are an estimated 1,200 pharmaceutical packagers, according to an FDA spokesperson, an unknown number of which are small. [236] Also unknown is the number of small firms that provide consumer-ready pharmaceuticals; some firms provide products only in bulk packages. The Commission expects that many of the small firms can use standard SAUE packaging. However, firms that use reclosable packaging may have to find new suppliers, and may also have to pay more for SAUE packaging. Films, foils, and other materials used for SAUE non-reclosable packaging also may cost more than the materials used for existing CRP. No comments were received from any small company regarding the possible need for stability testing to meet FDA requirements. Incremental costs for new packaging are expected to be modest and most likely will be passed on to users. CPSC does not anticipate that a significant number of packagers will be severely or permanently affected.

E. Pharmacies

There are over 40,000 independent pharmacies, according to a representative of the National Association of Retail Druggists, most of which are small businesses. [236] (There are an additional 25,000 chain pharmacies, including those associated with drug and food stores and mass merchandisers. *Id.*) Retail establishments may have to find new suppliers if old suppliers abandon the market or do not offer acceptable sizes of containers. Pharmacies may also have to pay more for SAUE packaging than for existing CRP. Pharmacy staff probably will spend additional time instructing customers in the use of new packaging. Modest incremental costs for SAUE packaging and for staff time are likely to be passed on to the consumer, and there should not be a big impact on most pharmacies.

F. Conclusion

The Commission concludes that the action to revise the testing protocol for special packaging under the PPPA will not have a significant adverse impact on a substantial number of small businesses.

IX. 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 revisions to the PPPA protocols.

The Commission assessed the possible environmental effects of rulemaking associated with the revisions to the protocol for testing CRP under the PPPA and presented its findings in a paper dated April 2, 1990. [123, Tab D] Reassessment of the possible environmental effects confirms the original determination that the rule will have no significant effects on the environment. [236] The revisions to the rule involve a test method and establish new test standards. They will not change the number of CRP in use. Since the rule will not become effective until 1 year after its publication and there will be a subsequent 18-month blanket exemption from compliance, there is time to use up existing inventories of unfilled non-SAUE packaging. Additionally, SAUE packaging is made of basically the same materials and in basically the same way as older styles of CRP. Much of the existing equipment involved in the production and filling of non-SAUE packaging can be modified to produce SAUE packaging, rather than replaced.

EFFECTIVE DATES: Revised §§ 1700.15(b)(2), 1700.20(a)(3), and 1700.20(a)(4) are effective July 22, 1996. Until then, current §§ 1700.15(b)(2), 1700.20(a)(4), and 1700.20(a)(5) remain in effect.

Revised §§ 1700.20(a) (1) and (2) are effective January 24, 1996. Until then, current §§ 1700.20(a)(1)–(3) remain in effect.

New § 1700.20(d) is effective August 21, 1995.

For mandatory provisions, the effective dates specified above apply to all products subject to the respective sections that are packaged on or after the effective date.

List of Subjects in 16 CFR Part 1700

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

V. Conclusion

For the reasons given above, the Commission amends 16 CFR 1700.20 as follows:

PART 1700—[AMENDED]

1. The authority citation for Part 1700 is revised to read as follows:

Authority: 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. Section 1700.15(b)(2) is revised to read as follows:

§ 1700.15 Poison prevention packaging standards.

* * * * *

(b) * * *

(2) Ease of adult opening. (i) Senior-adult test. Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of § 1700.20(a)(3).

(ii) *Younger-adult test.* (A) When applicable. Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of § 1700.20(a)(4). The senior-adult panel test of § 1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

(B) Determination of need for metal or aerosol container.

(*1*) *Criteria.* A product will be deemed to require metal containers or aerosol form only if:

(*i*) No other packaging type would comply with other state or Federal regulations,

(*ii*) No other packaging can reasonably be used for the product's intended application,

(*iii*) No other packaging or closure material would be compatible with the substance,