of the children must be unable to open the package within the first 5 minutes, and at least 80 percent of the children must be unable to open the package by the end of the second 5-minute period. 16 C.F.R. 1700.15(b)(1).

B. Adult Test and Criteria

The current adult test protocol, 16 C.F.R. 1700.20(a)(4) and (5), specifies a test panel of 100 adults, ages 18 through 45 years. Seventy percent of the adults must be females and 30 percent must be males. For a package to meet the PPPA effectiveness criteria, at least 90 percent of the adults must be able to open and, if appropriate, properly close the package within the 5-minute test period. 16 C.F.R. 1700.15(b)(2).

C. Noncomplying Packaging

The Congress was concerned that some elderly or disabled persons would be unable to open CRP. Therefore, the PPPA was drafted to permit substances subject to CRP requirements to be marketed in non-CR packages (''non-CRP'') in certain circumstances.

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 of a popular size 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.'' Section 4 specifies that the reason for allowing non-CR packages is to make substances subject to CR standards ''readily available to elderly or handicapped persons unable to use such substance when packaged in (CR packaging).''

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 this case, 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.

Furthermore, prescription substances subject to special packaging standards may be dispensed in non-CRP if directed by the prescriber or requested by the purchaser. PPPA § 4(b), 15 U.S.C. 1473(b).

Thus, persons who find CRP unduly difficult to use may purchase the single size of a nonprescription product that may be provided in noncomplying packaging or may request that his or her prescriptions be supplied in noncomplying packaging, thereby eliminating the protection that CRP provides against poisoning.

II. CPSC's Changes to the PPPA Protocol

A. Procedural Background

Many consumers find CRP to be too difficult to use. When given the choice, therefore, many consumers purchase products in conventional packaging rather than CRP. [29] [1] Consumers are also making a substantial number of CRP ineffective after bringing them home, such as by leaving the package cap off or loose or by placing the package's contents in a non-CR container. [29] This failure to use or misuse of CRP is a substantial cause of accidental poisonings of young children.

On January 19, 1983, the Commission published an advance notice of proposed rulemaking (''ANPR'') outlining its concerns in this area and explaining possible actions to increase the proper use of CRP, simplify the test procedures, and make the test procedures less affected by possible variables. 48 FR 2389. After considering comments on the ANPR and other available information, the Commission decided to propose amendments to the protocol to address this problem. Also, the proposed amendments would change the protocol to make the test results more consistent and make the child test easier to perform. The Commission published its initial proposal in the **Federal Register** of October 5, 1990. 55 FR 40856.

The original period for written comments on the proposal expired January 3, 1991, and oral comments were received by the Commission on December 5, 1990. The written and oral comments included several requests that the comment period be extended for periods up to 180 days. The requests stated that the testing and evaluations needed to respond to the proposal required the additional time. Some requests also asked for a second opportunity to submit oral comments at the end of the extended period for submitting written comments.

The Commission considered these requests and granted an extension of 180 days, until July 1, 1991, for submission of written comments. Additional oral comments were received on September 12, 1991.

During the original comment period, a commenter suggested certain changes to the proposed adult test. The Commission preliminarily concluded that this suggestion might have merit and requested comment on it. 56 FR 9181 (March 5, 1991).

The Commission received a number of comments in response to the proposed rule and the additional request for comment. The Commission also contracted for additional testing to obtain information to address the comments received on the proposed 5-minute/1-minute test. The Commission then published a further request for comment on additional information used to address comments and on the changes to the test procedures that the Commission preliminarily concluded were appropriate. 59 FR 13264 (March 21, 1994). The Commission denied three requests for extension of the 60-day comment period on that notice.

On January 5, 1995, the Commission approved an amendment of its requirements for child-resistant packaging to change the child and adult tests under which child-resistant packaging is evaluated. Then, on February 6, 1995, the Commission approved a **Federal Register** notice to implement these changes. Immediately thereafter, the Commission was provided with comments on the final rule that had not previously been submitted to the agency during the course of the rulemaking. These comments were circulated by the Coalition for Responsible Packaging (the ''Coalition''), a recently formed ad hoc industry group.

The Commission voted on February 9, 1995, to withhold publication of the final rule in order to consider these new arguments. In order to provide interested parties with every reasonable opportunity to comment on the new issues, the Commission provided for both written and oral submissions. Written comments on these issues were to be submitted to the Commission by March 7, 1995 (60 FR 9654, February 21, 1995). The Commission also held a hearing on March 16, 1995, to receive oral presentations. The hearing was announced in the **Federal Register** of March 6, 1995 (60 FR 12165). After

[1] Numbers in brackets indicate the number of a relevant supporting document in the ''List of Relevant Documents'' in Appendix I to this notice.