

males. The test period is 5 minutes. The adults are given the test package and asked to open and then properly close the package. 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).

In enacting the PPPA, the Congress was concerned that the elderly or individuals with disabilities 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."

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. 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. The Commission was concerned that these consumer actions, all caused at least in part by packaging that is difficult for normal adults to use properly, were exposing children to avoidable poisonings.

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.

Older adults typically have the most difficulty with CRP. Therefore, in order to eliminate the currently-marketed CR package designs that are most difficult for "normal adults" of all ages to open, the Commission proposed to substitute older adults, ages from 60-75 years, for the current panel of 100 18-45 year-olds.

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 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). On December 20, 1994, the Commission was briefed by its staff on the comments on the proposed rule and the changes recommended by the staff.

On January 6, 1995, the Commission met and decided to approve the rule recommended by the staff, but to exclude from the scope of the rule those products that must be packaged in metal cans or aerosol form. The staff made appropriate changes to the draft **Federal Register** notice that would issue the final rule, and that notice was approved by the Commission on February 6, 1995. Immediately thereafter, certain portions of the packaging industry raised concerns about the Commission's action. Some of these concerns already had been addressed in the rulemaking proceeding. Two concerns, however, had not been the subject of specific comments by interested parties in this rulemaking.

Specifically, the new comments can be summarized as follows. First, in establishing an adult test panel consisting of adults aged 60-75, the Commission allegedly exceeded its statutory authority to require that child-resistant packaging not be difficult for "normal adults" to use properly. Second, the rule allegedly addresses consumer convenience, rather than safety, which the comment claims is not properly the subject of a Commission regulation. In addition, the second comment contends that to the extent that child-resistant packages exist that will pass the "senior friendly" test approved by the Commission, market forces will be an adequate and more appropriate mechanism to ensure that the more convenient packaging will be adopted.

The Commission wanted to assure that it had an opportunity to consider these new arguments that had not previously been raised in the rulemaking. Accordingly, on February 8, 1995, the Commission voted unanimously to withhold publication of the **Federal Register** notice that would have issued the final rule, to consider the new arguments. Written comments, limited to these two issues only, may be submitted until March 7, 1995. The Commission will consider any new information and arguments received on these issues alone, and will resolve these points as quickly as possible. Comments addressing other issues will not be considered.

Dated: February 16, 1995.

Sadye E. Dunn,

Secretary Consumer Product Safety Commission.

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