CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for the Special Packaging of Household Substances

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission amends its requirements under the Poison Prevention Packaging Act of 1970 (''PPPA'') for child-resistant packaging to change the child and adult tests under which child-resistant packaging is evaluated.

The revisions to the adult test will substitute 100 older adults, from 50 through 70 years old, for the current panel of 100 18–45 year-olds. The senior adults are tested to see if they can properly use the package in two test periods, 5-minutes and 1-minute. These changes will increase the use of child-resistant packaging by making it easier for adults to use properly. The revisions to the adult test do not apply to products that must be packaged in metal containers or in aerosol form, which will remain subject to the present 18–45 test panel and single 5-minute test period requirements.

The revisions to the child test include sequential testing, which can reduce the number of children that have to be tested in order to determine whether a package is child-resistant.

For all tests, the number of subjects tested by any one tester and the number of subjects tested at any one site are limited. Also, standardized instructions are required for the child and senior-adult tests.

DATES: Revised §§ 1700.15(b)(2), 1700.20(a)(3), and 1700.20(a)(4) will become effective July 22, 1996. There will be an additional 18-month blanket exemption from compliance with the new senior-adult requirements. Accordingly, packaging will not be required to comply with the senior-adult test until January 21, 1998.

Revised §§ 1700.20(a) (1) and (2), will become effective January 24, 1996.

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

ADDRESSES: Documents relating to this rulemaking proceeding may be obtained from the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Directorate for Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400, ext. 1368.

SUPPLEMENTARY INFORMATION:

Preamble—Table of Contents

I. The Current PPPA Regulations

The Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. 1471–1476, authorizes the Consumer Product Safety Commission to issue requirements that certain household substances be sold in ''special packaging,''hereafter referred to as child-resistant (''CR'') packaging. The PPPA defines CR packaging as ''packaging that is designed or constructed to be significantly difficult for children under five years of age to open * * * and not difficult for normal adults to use properly.''15 U.S.C. 1471(4) (emphasis added). Under the PPPA, the Commission has defined and established standards for CR packaging. 16 CFR 1700.1(b)(4), 1700.3, 1700.15, and 1700.20. The Commission has also determined which household substances are required to have CR packaging. 16 CFR 1700.14. The existing requirements were developed before the widespread use of CR packaging (''CRP'') and, therefore, without the benefit of the actual use experience and test data that since have become available.

A. Child Test and Criteria

The current child-test protocol (16 C.F.R. 1700.20(a) (1), (2), and (3)) specifies testing with 200 children, ages 42 through 51 months, distributed in 10 groups by specific ages. Each age group consists of approximately one-half boys and one-half girls. A pair of children are given test packages and asked to open them. If both children open their packages, the test is stopped. If at least one child has not opened his or her package after 5 minutes, the opening test is stopped and the children are given a single visual demonstration of the method of opening the package. If the children did not attempt to use their teeth to open the package during the first 5 minutes, they also are told at this time that they may use their teeth to open the package if they wish. Then, the opening test is resumed and continues for another 5 minutes.

For a package to meet the PPPA effectiveness criteria, at least 85 percent

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.

considering these comments, the Commission voted on June 15, 1995, to issue the revisions to the PPPA test protocols described in this notice.

The following sections of this notice describe the revisions that were proposed and the revisions that have been included in the final rule. Where the final rule differs from the proposal, the reasons for the changed provisions are stated in this notice.

There have been multiple opportunities for public comment in this proceeding, and providing another such opportunity is unnecessary and would substantially delay implementation of this important safety rule. Accordingly, the Commission concludes that the final rule should be issued without an additional opportunity for public comment.

B. Changes in the Adult Test Panel

Older Adults

The PPPA has helped to significantly reduce the number of childhood poisonings. However, after more than 20 years, many children are still being injured and killed by accidental ingestion of harmful products. In 1994 alone, an estimated 130,000 children under 5 years old were treated in hospital emergency rooms for suspected or actual poisonings. In 1993, poison control centers received reports of more than 6,300 poisonings of young children with effects that were either ''moderate'' (*i.e.*, pronounced and prolonged, generally requiring treatment) or ''major'' (*i.e.*, life-threatening). In addition, 42 children died in these tragic accidents in 1992, the most recent year for which the Commission has complete death data.

The Commission's data show that many CR packages are difficult for many if not most adults to use and that this is a substantial factor in accidental poisonings of young children. In a survey of about 3000 consumers, difficulty in use was the reason given by 42% of the 313 people who left the CR cap off, by 43% of the 389 people who transferred the contents to another container, and by 59% of the 232 who replaced a CR cap with a non-CR cap. [15]

This difficulty in using CR packaging is confirmed by other data in the record. Typical reclosable CR packaging that passes the current adult protocol was considered difficult to use by 22 to 64% of 800 people aged 18–45, depending on package type. [27, 28] Thus, reclosable CR packaging does not fully implement the PPPA's requirement that such packaging not be difficult for normal adults to use properly.

Furthermore, the data show that the improper use of CR packaging is involved in a substantial number of accidental ingestions by young children. For example, one statistical study of the accidental ingestion of medicines by young children showed that 17% of the medicines had been supplied in CR packaging but were not in properly secured CR packaging when ingested. [112] An additional 40% of the medicines in this study were not purchased in CR packaging.

In another study of about 2000 accidental pediatric drug ingestions, 18% of the reclosable containers had caps that were off or loose prior to the ingestion. [29, 92] Of the cases involving toxic drugs, about 6% involved CR closures that were left off or loose, about 17% involved contents transferred from one container to another, and about 18% involved non-CR packages.

Based on this type of data, the Commission concluded that reducing the misuse of CR packaging by adults would reduce the number of accidental poisonings among children, and that this could be accomplished by making CR packaging easier for adults to use. Accordingly, the Commission began a rulemaking proceeding in 1983 to achieve these goals.

The Commission concluded that substituting a panel of older adults, who as a group are less able to open traditional CRP, would exclude the more difficult-to-use designs that now can pass the test with the younger panel. The Commission proposed to substitute a panel of 100 older adults, ages from 60–75 years, for the current panel of 18–45 year-olds. Test participants were limited to those who could demonstrate the ability to open and resecure non-CRP. The Commission's rationale for this conclusion is discussed in more detail in section V(C) of this notice.

Age Groups

In the originally proposed rule, the senior test panel consisted of 100 adults between the ages of 60–75 selected at random. Several comments were received concerning the lack of a defined age distribution of the participants throughout the 60–75 age group. Commenters stated that a random sample would result in 50–60% of the participants being in the 71–75 year-old age group. The commenters placed special emphasis on the variability of the 71–75 year-old age group, as measured by the participants' time to open the packages. The commenters requested that the 71–75 age group be dropped from the test due to high variability and the lack of homogeneity.

To address the comments concerning distribution, the Commission's staff devised modifications to the test procedure that divided the 60–75 year-old age group into three age groups: 60–64, 65–70, and 71–75. This would assure a more uniform spread of subjects throughout the age range. For the reasons discussed below, the Commission decided to change the adult test to a panel of 50–70 year-old adults. Testing conducted in 1991–1993 confirmed that the 60–64 year-old group and the 65–70 year-old group tend to perform similarly. [184, 160] See 55 FR 40858, [27]. Because there was no statistically significant difference between the performance of the 60–64 and 65–70 age groups, they are combined in the final rule into one group covering ages 60 to 70. As discussed below, to reduce the risk that the test results of 50 to 59 year-olds will vary significantly with age, the Commission has decided to divide that group into two groups, one of ages 50–54 and the other of ages 55–59.

Sequential adult test.

Many comments on the originally proposed 100-member adult panel stated that although the Commission included data on packages that passed the 1-minute senior test with a senior-adult use effectiveness (''SAUE'') greater than 90%, the probability of these packages passing consistently was unknown. The commenters stated that SAUE of 95% in 1 test is required to assure that the package will pass consistently at 90%. Commenters stated that the protocol must be designed to avoid failing an effective package with a true proportion a little greater than 90%, or passing a package with a true proportion a little less than 90%. Various commenters suggested that this could be accomplished by eliminating the 71–75 year-old age group, or by decreasing the SAUE acceptance criterion to 85%. However, neither of these changes would address the variability of results with ''borderline'' packages.

To address these comments, the CPSC's staff developed a sequential testing scheme. That test would have maintained the age range of 60–75 years of age and the acceptance criterion of 90, while assuring a high level of confidence for passing packages. [174] The adults, under the staff's plan, would be tested sequentially, in panels of 100, until a statistically reliable pass/fail determination can be made or a total of 400 adults (4 panels of 100) was tested. Providing for a larger number of adults to be tested for packages that perform near the 90 percent criterion would

increase the likelihood of making the correct decision of passing or failing. The sequential testing procedure was published for comment in the **Federal Register** of March 21, 1994. 59 FR 13264.

Many of the subsequent comments indicated that the sequential testing scheme would produce a much greater testing burden on industry. For the reasons stated in section III(D) of this notice, the Commission agreed and reverted in the final rule to the current 100-adult test panel.

Senior Adult Use Effectiveness (''SAUE'')

Successful participants are those who open the test package within the first, 5-minute, period and also open and properly resecure the test package within the second, 1-minute, period. In the proposal of March 21, 1994, the proportions of success for the 60–64, 65–70, and 71–75 year-old age groups were calculated separately and averaged so that the larger 71–75 year-old age group was not more heavily represented. The SAUE was compared to the acceptance criteria for the sequential test to see whether the package has passed or failed or whether another panel of 100 should be tested. The SAUE was calculated in the same manner for 100, 200, 300, or 400 participants.

In the final rule, as noted above, the Commission specifies that the adult test panel shall consist of 100 adults of ages 50 through 70, inclusive.[2] The specified age categories within the 50 to 70 range are weighted according to sample size allocation. Accordingly, there is no longer a need to calculate the proportions of the age groups separately and average them. Therefore, if 90 or more of the adults on the test panel are able to properly use a package, it passes the adult test.

Screening Tests

The proposed rule stated that the senior test panel would be composed only of adults who have successfully passed 1-minute screening tests using non-CRP. The packages used for screening purposes are a non-CR snap and a continuous-threaded package. The participants have to open and to resecure the two non-CR packages within 1 minute for each package. People unable to open either of these packages do not participate in the test. The screening test was proposed to eliminate individuals with limited ability. The range of movement and strength required to open and close non-CR snap and continuous-threaded packages serves as the baseline for test participation.

Several commenters argued that the screening process should apply to people who failed to open the CRP during the first 5-minute test period. The testing firms indicated that participants were frustrated and confused by the number of packages they were asked to open. The CPSC staff adopted the practice of screening only those who fail to open the test package during the first 5-minute period in the testing conducted under contract CPSC–91–1135. The Commission amended the test procedures to incorporate this change.

Homogeneity

In addition to distribution and variability, comments were received about the lack of homogeneity of the 60–75 year age group. The commenters did not define the term homogeneity. Homogeneity is defined by the CPSC staff as the similarity of the subjects of different ages within a particular age group in their ability to successfully open and resecure the various CRP. The CPSC staff statistically analyzed the homogeneity of the three age groups, using the results of tests with reclosable and non-reclosable packages. [187, 188] No significant differences were found in performance within each of the three age groups (60–64, 65–70, and 71–75) for either reclosable or non-reclosable packages. Therefore, no changes to the test procedures are required with respect to the homogeneity of the age groups within the 60 to 70 age range. As noted, the age range of the adult panel in the final rule is 50–70. The data discussed above show there is homogeneity in the 60–70 age range. To reduce the practical effect of any potential lack of homogeneity in the 50–59 age range, the Commission specified that 25 persons would come from the 50–54 age range and that another 25 would come from the 55–59 age range.

C. Adult Test Times

The 5-minute test time of the current adult test probably greatly exceeds the time that consumers are willing to spend attempting to open a CR package. The frustration level experienced by persons trying to open a package depends on both the effort and time required to do so. [132] The Commission proposed that the effort required to open and, if appropriate, resecure CRP should be reduced by requiring that closures can be opened and resecured by adults older than the currently required 18–45 age group. In order to ensure that CRP is not so difficult to use that adults must spend an unreasonable amount of time trying to open and close the packaging, the Commission proposed to reduce the time period for the adult test to 1 minute. Shortening the test time will help ensure that CRP is acceptable to users and will therefore be used properly.

In order to allow the use of new packaging designs that are unfamiliar, the originally proposed 1-minute opening/resecuring test would have been preceded by a 30-second period that the test subject could use to become familiar with how the package operates. During the original comment period, a commenter suggested that the proposed 30-second familiarization period be extended to 5 minutes and that the test subject must be able to open the package during that time. The subjects who were successful in opening the package during the familiarization period would then be tested to see if they could then open and, if appropriate, resecure the package within 1 minute. Subjects would have to be successful in both time periods in order for the package to pass the adult test. The commenter suggested that the longer familiarization period would allow time for test subjects to learn how to operate unfamiliar designs. The Commission preliminarily concluded that this suggestion might have merit and requested comment on it. 56 FR 9181. The final rule incorporates this suggestion.

D. Changes to Simplify the Child Test

Other proposed amendments were intended to simplify the current child-test procedures, without reducing the ability of the test to determine child-resistance. These proposed amendments included testing for child-resistance by using sequential groups of 50 children, rather than using the full 200-child panel each time, until a statistically valid determination of whether the package is CR is obtained, or until the current number of children tested, 200, is reached. Also, the Commission proposed to use 3 age groups, of 42–44, 45–48, and 49–51 months, with 30, 40, and 30% of the children in each age group, respectively, instead of the current 10 age groups between 42 and 51 months.

A comment was received requesting that the calculation of age be based on ''near age'' rather than on the month in which the child was born, as in the original proposal. The commenter indicated that ''near age'' makes it possible to calculate a child's age plus

[2] Elsewhere in this notice, the terms ''50 to 70'' and ''50–70'' mean ''50 through 70, inclusive.'' The same sort of terminology applies to the other age ranges mentioned in this notice, e.g., 18–45.

or minus 15 days. If the month of birth is used, the distribution could range from plus or minus 30 days.

The current PPPA test procedures defined in 16 CFR 1700.20(a)(1) indicate a distribution of children by ''nearest age.'' The term nearest age was not included in the revisions as originally proposed. The CR package testing contracted by CPSC uses a standardized formula for the calculation of the children's age to the ''nearest'' month. In response to the comment, the March 21, 1994, proposal included a calculation for near age as part of the child-test procedure.

These child-test changes are procedural and are not expected to change the test results. Accordingly, these changes will have no effect on the ability of currently available CRP to meet the effectiveness criteria.

E. Changes to Ensure Test Consistency

Other proposed amendments were intended to ensure that the test protocol produces more consistent results. These amendments are: to add an optional procedure for determining whether the package has been secured adequately by the adults; to limit the number of subjects that could be tested by any one tester to no more than 30% of the children or 35% of the adults (in both the senior- and younger-adult tests); to limit the children in each group who are tested at or obtained from any given site to not more than 20%; to limit the percentage of the total number of senior adults tested who are tested at or obtained from any given site to not more than 24%; to limit the total number of younger adults obtained or tested at any one site to 35%, and to issue guidelines for standardized instructions to be used when testing.

The current PPPA regulations do not include the test instructions used by CPSC for the child and adult test. The Commission originally proposed adding a recommendation to § 1700.20 for the use of standardized instructions as voluntary guidelines for conducting the child and adult tests. The Commission received comments supporting standardization of the test procedures.

The Commission agreed that the procedures and instructions for the senior and child tests should be followed closely to ensure the statistical reliability of these tests and to control variability. Accordingly, the Commission's March 21, 1994, **Federal Register** notice proposed to include standardized instructions for the child and senior-adult tests in the rule.

F. Adult-Resecuring Test

The PPPA requires that adults be able to use CRP properly, which includes both opening the package and resecuring it to a CR condition. The adult-resecuring test proposed by CPSC can be used to determine whether packages have been properly resecured when an objective determination that this has occurred (e.g., visual or mechanical) cannot otherwise be made.

When such packages have been opened and appear to be resecured during the adult test, they are given to children to open according to the child-test protocols. If more than 20% of these children succeed in opening the packages, the number of children in excess of 20% count as failures to resecure by adults.

III. Comments on the Proposal

Thirty-six commenters submitted information and comments in response to the March 21, 1994, **Federal Register** notice. The comments focused on several areas, including the availability of test subjects, the cost of package development and testing, and the effective date for implementation. In addition, the Commission received 21 comments in response to the February 21, 1995, **Federal Register** notice concerning the issues that had not been raised previously in the rulemaking. (These issues are: (i) Older adults are not ''normal adults'' under the statute and therefore must be excluded from the adult test panel, and (ii) the revised protocol allegedly addresses convenience rather than safety.) Also, nine persons spoke at the oral hearing on March 16, 1995. Furthermore, more data and arguments concerning the new issues were provided in correspondence and meetings after these opportunities for comment. The Commission's response to these comments and to other comments received previously but not addressed, is given below. Comments on economic issues are addressed separately in section IV of this notice.

A. Child Test Protocol Changes

The only change to the previously-proposed child test protocols by the March 21, 1994, **Federal Register** notice was to make the standardized test procedures part of the rule rather than suggested guidelines. The Commission received comments on the standardized test procedures and also received comments on aspects of the child test that have been in effect for over 20 years. The comments on the child test protocols, and the Commission's responses, are described below. Comments made about child testing of unit packaging are addressed in section III(B), below.

Consent Forms

Several commenters indicated that the mandatory use of informed consent for child protocol testing will decrease the population of children available for testing and increase the time and cost of testing. Commenters contended that the Commission tried to require informed consent in the late 1970's but withdrew the proposal based upon the comments that were received at that time. Some commenters requested that all mention of consent for children be eliminated from the revised protocol. Other commenters indicated that the protocol should state that informed consent should be required only if required by the contracting party or testing agency.

In 1972, the Commissioner of the Food and Drug Administration (''FDA'') proposed amending the CR test procedure to require informed consent (37 FR 26833). This proposal was withdrawn in 1979 by the Commission because general U.S. Government regulations for the protection of human subjects made specific PPPA human subject requirements unnecessary (44 FR 55310). The CPSC is required by the regulations for the Protection of Human Subjects (16 CFR 1028) to use informed consent in all human testing conducted by or for the agency. Therefore, the statement that each child's parent or guardian should read and sign a consent form prior to testing was included in the rule to ensure that the test specified in the standard is the same procedure that CPSC must use for compliance purposes.

Because informed consent must be used in CPSC-sponsored testing, the Commission does not believe that the statement about informed consent should be deleted from the test protocols as requested by one commenter. Commenters stated that most child testing is done without informed consent. The Commission has no data showing whether there are differences in test results conducted with and without informed consent. Therefore, the final rule differs from the proposal in that the final rule states that the Commission will not disregard results of child tests performed by other parties simply because the tests were conducted without informed consent.

Test Sites

The proposed child test procedure states that the testing should be done in a location that is familiar to the children; for example, their customary nursery school or regular kindergarten.

No more than 20% of children in each group shall be tested at or obtained from any one site.

Commenters requested that child testing be allowed to be performed at one or more central locations, provided the children are drawn from a variety of locations within the geographic area and the children are made to feel comfortable at the test site.

Although this approach might make it easier to conduct the tests, the Commission has concerns about the effect of unfamiliar surroundings on CR package testing. The current regulations contain the requirement for familiarity; therefore, all data collected for the past 20 years were collected from tests conducted in familiar surroundings. It is not known what influence unfamiliar surroundings might have on a child's participation in the test, and the commenter did not provide data on this issue. For example, a child may be distracted during testing because of being separated from a parent in a strange place, or by being paired with another child who is a stranger rather than a classmate. Therefore, testing will continue to be conducted at five sites familiar to the children.

Sample Preparation

Commenters indicated that the sample preparation sections of the child and senior tests should be consistent. The Commission agrees and has modified section 1700.20(a)(2)(iv)(1) of the child test instructions to state:

> Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (*e.g.*, the closure liner) to ''take a set.'' Application torques must be recorded in the test report.

The proposed child-test instructions also stated that reclosable packages shall be opened and properly resecured one time by the tester who will be conducting the test. Commenters requested that testers resecure torque-dependent packages to a specified torque prior to testing the samples with children. Commenters voiced concern that test results would depend on the strength of the tester and not on only the child/package interaction.

The Commission opposes resecuring packages that are to be child tested to a specified torque, because the preparation of samples is designed to mimic the situation found in the home. Testing packages with a specific application torque only represents the child-resistance at that torque and above. Machine application torques only represent the first opening and not how the package will be available to the children in the household most of the time. Having people resecure the packages prior to testing better mimics the home situation. The commenters provide no information about what criteria would be necessary to determine the appropriate torque in this case. The Commission agrees, however, with comments stating that it is not necessary for the same tester who conducts the test to open and resecure the packages before testing, and has modified the instructions in the final rule accordingly.

The commenters also indicated that test instructions should include a test to determine that a CR package will continue to function for the number of openings and closings customary for its size and contents, as required by the current PPPA regulations. The Commission agrees with this comment and has added the standard procedure for multiple openings/resecurings used by CPSC in Instruction 3 of the Child Test Instructions.

Child Test Instructions

Several comments were received regarding the child test instructions. Most of these comments requested clarifications of the instructions printed in the March 1994, **Federal Register** notice. Several minor changes to wording of the instructions have been made by the Commission in response to these requests and suggestions.

Seating

One comment concerned the statement in the instructions that children are required to sit in chairs. It was requested that this statement be deleted because chairs are not practical for testing large or tall containers. The Commission agrees that chairs may make it difficult for children to handle large or tall containers. Therefore, the Commission has changed instruction 6 of the child test to read ''The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.''

It is important, however, that tests be conducted consistently. If a large or tall package is tested, all the children tested should sit on the floor. If a table and chairs are used, all children tested should be tested at tables and chairs. This does not restrict the children from freedom of movement during the test as indicated in the test instructions. The Commission recommends that testing agencies note on the data sheets and in the test report whether children have been tested on the floor or in chairs.

Use of Teeth

Children often use their teeth to try to open packages when they are at home. It is therefore important to determine whether CR packaging can be opened by children when they use their teeth. However, children may feel inhibited about doing so during the test. Accordingly, the current child test procedure states that if one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say, ''you can use your teeth if you want to'' before the start of the second 5-minute test period. Some commenters requested that the instruction to use teeth be given before the demonstration instead of after. These commenters request moving the statement because when the instruction is given immediately before the second 5-minute test period, the children do not try to open the packages as the tester demonstrates but put the packages immediately into their mouths. The commenters contend that the present order of instructions minimizes the effect of the demonstration and emphasizes the permission to use teeth. The commenters want to separate the instruction that teeth can be used from the demonstration of how to open the package.

The Commission disagrees with the solution proposed by these commenters. The suggested change would simply reverse the impact by giving the statement that teeth can be used at the end of the first test period, after children have put the package down. The subsequent demonstration may negate the effect of the permissive statement.

There may be better ways to address these commenters'' concern that the teeth-using instruction be separated from the demonstration so the children will have an opportunity to model the tester's actions. For example, the timing, rather than the order, of the instruction regarding teeth could be altered (*e.g.*, one minute after the demonstration). [234] However, it is not known whether this would actually better mimic the situation that exists in the home. Furthermore, the effect of this modification on test results is unknown, since a shorter time period would be available for children to use their teeth. For unit packaging, this could affect the quantity of product children access during testing. As with the commenters' proposal, such a change could result in future test outcomes which differ significantly from those obtained in the past.

The Commission concludes that the stringency of the child-resistance test should not be increased or decreased

without a demonstrated need to do so. Should data become available in the future to clarify the impact of such a change to this portion of the protocol, the Commission can consider this issue further.

Some commenters requested that, after the test, the tester say, ''I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN.'' The Commission considers this to be acceptable. However, testers must remember to modify this statement if the children used their teeth before the demonstration. The child-test instructions in the final rule incorporate these changes.

B. Unit Packaging—Non-Reclosable

Several comments were received regarding the proposed test protocols as they relate to unit packaging. A commenter indicated that it is not possible to make senior-friendly unit-dose packaging that is CR. Commenters provided alternative suggestions: maintaining the existing 18- to 45-year-old test group for unit packaging, amending the child test protocols to eliminate the use of teeth, or reducing the age of children tested. The Commission does not believe that these commenters' suggestions are necessary or warranted. Responses to individual issues related to unit packaging are addressed below.

Child-Resistance

Commenters indicated that the test for child-resistance is too stringent for unit-dose packaging because the children are told to use their teeth, and the children tested are much older than 2-year-olds (the average age of the children ingesting substances).

The Commission disagrees with these comments. Children use their teeth to open packaging. However, they are less likely to do so in front of an adult stranger. [234] Therefore, the statement about teeth is an important part of the test because it may lessen the inhibition a child may feel while being watched by a stranger. The commenters have provided no information to support eliminating the statement about teeth from the child-test protocol.

The commenters indicated that the children tested are older than the at-risk population of 2-year-olds who are involved in almost half of the poisoning incidents. The commenters state that the best way to have senior-friendly packages is to test only the population of children most at risk. Alternatively, the commenters request that the test with older children be ''calibrated'' by decreasing the time of the test or changing the pass/fail rates.

The Commission disagrees with these comments. The PPPA is intended to protect children less than 5 years of age from serious injury from handling, using, or ingesting hazardous household chemicals. 15 U.S.C. 1471(4). Changing the age of the children to 2-year-olds would leave the older children unprotected. The current protocol, which has been used for the past 20 years, already excludes children 52 to 59 months old, who are the most capable children in the population at risk. The test also allows a liberal 20% failure rate. Lessening the CR standards by decreasing the age of the children tested, lessening the time of the test, or decreasing the standard for child-resistance would lessen the protection that the PPPA was intended to provide.

Several commenters indicated that unit-dose packaging is inherently CR because children have to open individual blisters. The commenters cite the European standards, which allow opaque blister packaging to be considered CR. Commenters indicated that these packages are easy for adults to open and do not endanger children.

The definition of child-resistance for unit packaging under the current PPPA regulations can depend on the toxicity of the product being packaged. A test failure for unit packaging is any child who opens or gains access to the number of units that constitute the amount that may produce serious personal injury or illness or to more than 8 units, whichever number is lower. 16 CFR 1700.20(a)(3).

Test data with different ''non-CR'' unit packaging types indicate that 80–90% of children can access at least one unit. If this unit contains a product toxic enough to cause serious effects in a child, there is no child-resistance. These products do exist. This point was illustrated by Rosanne Soloway, representing the American Association of Poison Control Centers, at the December 5, 1990, presentation of oral comments. Ms. Soloway described scenarios where accidental ingestion by children of only one tablet of certain medicines resulted in coma and brain damage. Unit packaging that will not pass the tests for child-resistance is not inherently CR.

Commenters state that it is important that seniors have packaging to help them take their medications. One commenter indicated that unit packaging is an important mechanism of patient compliance and gave mnemonic oral contraceptive packaging as an example of successful packaging. These hormone-containing products were exempted from the CR requirement or oral prescription drugs because they have low toxicity. 49 FR 44455. However, children do ingest these products despite their being marketed in unit-dose packaging. Poison control centers report that almost 10,000 children a year ingest birth control pills without serious problems. [263] To define all unit packaging as CR would sacrifice the protection of children in order to promote better drug compliance. The Commission believes that a better approach is to improve unit packaging so that both purposes can be achieved.

Senior-Adult Use Effectiveness

Some commenters requested that unit packaging should be exempted from the senior test because there is no ''effective technology to deliver blister/pouch security without adult tool usage.'' The Commission does not agree with this statement. A blister package and pouch that do not require the use of a tool to open were tested by 60 to 75 year-olds as part of the CPSC testing program. [157, 159, 194] The results, which appeared in the March 21, 1994, **Federal Register** notice, demonstrate that it is possible to make senior-friendly, CR, unit packaging that does not rely on the use of a tool. Furthermore, the Commission is not averse to the tool concept, because many package types, especially food packaging, require the use of a tool to open. Rather than exempting unit packaging from the revised adult test requirements, the Commission believes that a better approach is to give proper instructions for opening a package, especially when a tool is required.

Some commenters claimed that the amount of time it takes older adults to open CR blisters contradicts CPSC's statement that the majority of participants thought these packages were ''easy to use.''

The statement that the majority of participants thought that the test packages were ''easy to use'' was derived from asking the participants to rate the package on a scale of 1 to 5 following the test. [194] The ease-of-use determination is based on the opinion of the participant and not on the actual time to open the package. The average opening times for the blister package were 40 seconds and 20 seconds for the first and second test periods, respectively. The commenters compared this to the average time for seniors to open a non-CR unit packaging, which was approximately 20 and 10 seconds for the two test periods. It should be noted that, although the times to open non-CR blister packages averaged 20

seconds, the actual times ranged from 2 to 90 seconds. The Commission believes that ease of use of unit packaging can be improved by giving clear opening instructions.

Failure for Unit Packaging

Some commenters requested that the limitation of more than eight units be eliminated from the child test definition of failure.

The current regulations state that a test failure for unit packaging is any child who opens or gains access to the number of individual units that constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. 16 CFR 1700.20(a)(3). The original PPPA regulations defined five units as a failure. This was established to provide the packaging industry with parameters for the development of unit packaging, but it was found to be too restrictive. The number of units was changed to eight in 1973 (93 FR 12738). The concern at that time was the uncertainty of determining the amount of a product that produces serious personal injury or illness to a child.

The commenters did not provide any test or other parameters for determining what amount of product in excess of eight units would cause serious effects in children. This would have to be done before this comment could be implemented. If such information becomes available in the future, the Commission may reconsider this issue.

Certain commenters requested clarification of the term ''opens or gains access.'' A unit-dose packaging trade association proposed a definition of failure for solid dosage forms in unit-dose blister packaging. The suggested definition would not cover liquids or items that can cause significant harm to children in small amounts. The suggested definition focuses on the absolute amount of the product removed from the package during the test and not the potential for removal. A blister with the backing removed and the pill totally exposed but not removed would pass, according to the commenters' definition. However, in that case, the product would be accessible to children. A puncture made by a child's tooth in a blister that contains a hard tablet may not allow the child access to the pill. However, the same tooth puncture in a blister with a tablet that can be easily pulverized and sucked out by the child is accessible.

The Commission is not adopting the commenter's proposed definition, but the test results can be interpreted in accordance with the discussion given above. The Commission is including the following language to clarify the meaning of ''opens or gains access to'': ''The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part.'' This is a modified version of language submitted by a another commenter. If companies have questions concerning individual products, the Commission's Office of Compliance is available to discuss these issues.

C. ''Innovative'' or Novel Packaging

Several commenters indicated that a separate test method should be employed for novel or innovative packaging. Failure of novel designs to pass the 5-minute/1-minute senior test is interpreted by these commenters as a flaw of the test because it does not take into account the unfamiliarity of the package. Other commenters indicated that, for novel packages, participants should be told that the packages they are testing are not like the ones they have at home and that they should follow directions very carefully.

The purpose of the PPPA protocol revisions is to ensure the availability of CRP that normal adults, including older adults, can use without difficulty. It is contrary to the purpose of the regulation to adopt a separate, less stringent, test procedure to promote new designs that do not meet the minimum standards.

Giving participants the information that the packages they are testing may be unfamiliar to them is reasonable. However, additional emphasis on the instructions for novel designs, or admonitions to follow them very carefully, are inappropriate since this situation would not occur in the home.

It is better to present the information, that the designs may be unfamiliar, in a standard format. The description of the test in the consent form is appropriate for this purpose. Accordingly, the Commission is adding the following sentence to the consent form: ''You may or may not be familiar with the packages we are testing.''

D. Senior Test

A number of comments were received regarding the senior test. These comments are discussed below.

Normal Adults

One of the two new comments that were received after February 6, 1995, was that older adults are not ''normal adults'' under the statute and therefore must be excluded from the adult test panel. This issue is discussed below.

1. Introduction and background. The PPPA was enacted in 1970 to reduce the number of deaths and injuries to young children who accidently ingest poisonous products. It authorized the Department of Health, Education, and Welfare (''HEW'') to issue CR packaging requirements for such substances. In 1973, this authority was transferred to the newly-created CPSC.

In addition to providing that special packaging must be significantly difficult for children under age 5 to open, section 2 of the PPPA requires that the packaging must be ''not difficult for normal adults to use properly'' (emphasis added).[3] This adult requirement reflects Congress' concern that if CR packaging were difficult to use, people would fail to put the caps back on correctly or would transfer the contents to non-CR containers. The PPPA also accommodates those adults who are unable to use CR packaging by allowing companies to make non-CR packaging for such individuals in certain circumstances.[4]

The PPPA itself does not define the term ''normal adults,'' nor does it establish any procedure to determine difficulty of adult use. However, the PPPA's legislative history defines the term ''normal adults'' as ''the broad range of the adult population not having handicaps hindering their [proper] use of special packaging'' (emphasis added). S. Rep. No. 91–845, 91st Cong., 2d Sess. 9 (1970) (''S. Rep. No. 91–845''). To avoid limiting the development of technology, the PPPA contemplated that performance standards would be established to evaluate the child-resistance and adult-use effectiveness of child-resistant packaging designs.[5] As the Senate Report notes, the statutory definition of child-resistant packaging expressly leaves it to the Commission to determine the parameters of special packaging in each case.[6]

The current protocol attempts to ensure that CR packages are not difficult for normal adults to use by requiring that the packages must be able to be opened and, if appropriate, properly closed within 5 minutes by 90% of a panel of 100 persons, 18 to 45 years of age, with no overt physical or mental handicaps. 16 CFR 1700.15, 1700.25.

The test protocol adopted by the Commission, which tests whether 50–70

[3] 15 U.S.C. 1471(4).

[4] 15 U.S.C. 1473.

[5] Thus, the law prohibits the Commission from specifying specific package designs, product content, or package quantity. 15 U.S.C. 1472(d).

[6] S. Rep. No. 91–845 at 9.

year-olds are able to open CR packages, is a surrogate for whether normal adults of all ages will have difficulty using such packaging. Certain commenters contended, however, that it would be unlawful to include older adults on the panel because they allegedly are not ''normal adults'' under the statute. These commenters further argued that section 4 of the PPPA exempts the ''elderly'' and ''handicapped''[7] from being considered as ''normal adults.'' The Commission disagrees with these claims that older people are not normal adults or that the proposed panel is unlawful.[8]

2. The term ''normal adults'' does not exclude all *''elderly'' persons.* The statute does not define ''normal adults.'' However, the legislative history of the PPPA indicates that the term normal adults is not limited to the 18–45 year-olds who make up the current test panel.

> ''The definition of special packaging leaves it to the Secretary [of Health, Education, and Welfare, now the Commission] to determine specifically the parameters of special packaging in each case. The [Senate] Committee [on Commerce], however, set limits to the parameters by specifying that special packaging must be significantly difficult [for children] to open . . ., that it need not keep out all children, that it not be difficult for normal adults—the broad range of the adult population not having handicaps hindering their use of special packaging to use properly, and that the target age-group is children under six [five, as enacted] years of age.''

S. Rep. No. 91–845 at 9 (emphasis added). Any claim that the term is limited to persons age 45 and below is inconsistent with this description of normal adults. Furthermore, the description of ''normal adults'' as including ''the broad range of the adult population'' implies that there will be considerable variation in the abilities of persons across that range.

In addition, human factors considerations also indicate that the broad range of normal adults includes the elderly. The Division of Human Factors notes that there is considerable overlap in the physical capabilities of younger and older adults. [287]

One industry commenter appeared to equate normal adult with the ''norm'' of the adult population, and questioned how that can be determined if only the ''extremes'' of the population are tested. The Commission's Human Factors staff noted that the commenter inappropriately applied the concept of norm. The term norm, as used by the commenter, is a point value and cannot be used to determine the qualities of a range, such as the capabilities of normal adults. If norm were interpreted only as the average (*i.e.*, mean) value, it would be age 41 for the U.S. adult population. If norm were interpreted as the most common age, it would be age 29 for the U.S. adult population. Under either interpretation, structuring a test panel comprised only of subjects of a single age would be impracticable and uninformative about large segments of the population. Moreover, the age chosen could change with each census. Another commenter similarly described ''normal'' as only those of average or better capabilities. Because average is typically the halfway point, this commenter would exclude half the population from being considered normal. Congress could not have intended such results.

Also, the 60–75 test panel does not consist of the upper extreme, which generally is considered to be the 95th percentile of the studied population. According to Human Factors, the 95th percentile of U.S. adults is above age 75. Thus, the revised protocol specifically excludes the extreme.

3. Section 4 of the PPPA does not limit the meaning of ''normal adults'' in section 2. Some commenters argued that section 4 of the PPPA, in effect, defines normal adults to exclude the ''elderly'' or ''handicapped.'' This is incorrect.

As explained above, section 4 allows manufacturers and packagers to market regulated substances in non-CR packaging in certain circumstances. The reason for this exemption is to make ''any household substance which is subject to a standard * * * readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard.'' 15 U.S.C. 1473(a) (emphasis added).

There will always be people who, regardless of the adult test protocol in force, cannot use CR packaging. This is the segment of the population—whose size is determined not by age but by the state of the art of CR packaging and the degree of difficulty allowed by the standard—that non-CR packaging is intended to serve. Section 4 simply assures that companies will be permitted to make non-CR packaging available to these people. It does nothing more.

Certain industry commenters interpreted section 4 to mean that the statute divides the entire adult population into three distinct groups: ''normal adults,'' the elderly, and the disabled. These commenters argue that section 4 defines ''normal adults'' to exclude elderly people, and that they therefore may not be on the test panel. This argument is based on the premise that section 4 defines the term ''normal.'' However, it does no such thing.

One of these commenters has also argued that section 4 is designed to make packaging available not only to the elderly or disabled, but to all adults for whom ''child resistant packages would be difficult * * * to open.'' [277, pp. 2–3] While it is true that section 4 is designed to assist anyone who cannot open CR packaging, this is inconsistent with the argument that section 4 defines the term ''normal adult.'' That is, if section 4 defined ''normal'' and if it excluded the elderly, disabled, and anyone else who had difficulty using CR packaging, then each of these groups would have to be excluded from the test panel. However, this would mean that every CR package would pass the adult test with a score of 100% because anyone who had difficulty opening the package would, by definition, be ineligible to test it.

The debate between the two houses of Congress concerning the scope of the exempt size provision of the act also provides insight concerning the population of adults that Congress regarded as being normal. The House of Representatives favored a provision that would have made CRP the exception rather than the rule, requiring CRP for only one size intended for use in households with young children. This position was based on data indicating that 75% of all U.S. households had no children between the ages of 1 and 5. According to the House rationale, requiring members of these households to purchase products in CRP would be illogical. H.R. Rep. No. 1642, 91st Cong., 2d Sess. 6 (1970). Thus, the adults whom the House expected to use child-resistant packaging were those who actually had children, i.e., adults roughly 18 to 45 years of age.

The Senate, on the other hand, recognized that the problem of accidental poisoning was not limited to the immediate households in which children reside. It therefore favored legislation that would generally require CRP for all products subject to CR standards, with a limited exception providing non-CRP for those individuals physically unable to use products in CRP. S. Rep. No. 91–845 at 11. Under

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[7] The term ''handicapped'' is hereafter referred to as ''disabled,'' except where context requires the use of the statutory term.

[8] It should be noted that the Coalition for Responsible Packaging and its members were the proponents of this argument with respect to the previously proposed panel of 60–75 year-olds. However, the Coalition has publicly endorsed the Commission's decision to adopt a panel of 50–70 year-olds. [299] Thus, these industry commenters apparently now agree that the adult panel adopted by the Commission is permissible under the PPPA.

this scheme, since virtually all product sizes would be child-resistant, adults of all ages, as opposed to only those who had children, were the expected purchasers. Incapacity, not age alone, determined the parameters of the exempt size provision. Ultimately, the law as enacted adopted the Senate approach. Thus, the Congress clearly intended that ''normal adults'' include persons older than persons expected to have young children in their homes.

4. Even if section 4 did limit the meaning of ''normal adult,'' only those persons unable to use CR packaging would be excluded. To argue that all elderly or handicapped persons are excluded from being ''normal adults'' is to ignore the statute's qualifying phrase that section 4 is for persons ''unable'' to use CR packaging. Thus, even if section 4 were a limitation on the meaning of normal adult, which it is not, only those elderly or disabled persons who lack the capability to use CR packaging would be excluded.

Some commenters claimed the Commission's interpretation of ''normal adults'' eliminates the concept of age from the definition of ''normal adult,'' in contravention of the use of the term ''elderly'' in section 4. This argument is incorrect. The term ''elderly * * * unable to use'' in section 4 acknowledges that the sorts of ailments that may be associated with or caused by advanced age can render people unable to use CR packaging. However, section 4 simply cannot be read to exclude all elderly adults from being normal adults.

An industry commenter also argued that if the test panel is to include older adults, it must at least ''exclude those elderly persons who could not open'' CR packaging. [277, p. 4] This could be accomplished, according to the commenter, through a pre-test by ''giv[ing] the panel member the CR package * * * and exclud[ing] those elderly persons, who could not open it from the test group.'' [277, p.4] However, as discussed above with respect to another comment, if all older adults who failed to open the CR package were excluded from the panel, every package could, and in fact would be guaranteed to, pass with a perfect score.

Even in the 18–45 age group, there are persons who are disabled to the point that they cannot open CR packaging. The current test protocol, issued by the FDA in 1971, specifies that the adults on the panel shall have ''no overt physical or mental handicaps.'' 36 Fed. Reg. 22151 (November 20, 1971); 21 C.F.R. Part 295 (1972), now codified at 16 CFR 1700.20(a)(4). This prohibition of overt disabilities was the only condition in the original test protocol that would bar the participation of ''handicapped'' persons within the specified age range. Accordingly, people are permitted to participate in the current adult test even if they have disabilities that are not overt—*e.g.*, certain forms of arthritis—but may still affect their ability to open CR packages. Thus, FDA did not feel compelled by the reference to the ''handicapped'' in section 4 to exclude all disabled persons from the category of normal adults. Similarly, even if section 4 limited the definition of ''normal,'' not all older adults would have to be excluded from the adult panel.[9]

Finally, a commenter argued that the greater difficulty older adults have in opening traditional CR packaging proves that they are inherently disabled compared to younger adults and therefore cannot be considered ''normal'' adults. As explained above, however, just because the older participants'capabilities may be somewhat diminished in the use of traditional CR packages does not mean those adults fall outside the ''broad range'' of the adult population. Moreover, the commenter's argument overlooks the fact that the older adult panel can perform at a very high level—scoring 95% and above in CPSC tests—with packages that pass the revised protocol. Thus, under any interpretation, older adults do not have a less than normal ability to open the new type of CR packages.

5. The Commission is vested with broad discretion to establish the test protocol and criteria to determine whether packaging is not difficult for normal adults to use. Obviously, there is no one performance criterion that establishes a single point at which packaging transforms from difficult to not difficult for normal adults to use. Nor does the statute specify a point at which packaging will be deemed ''not difficult for normal adults to use.'' Congress gave the Commission broad discretion to address these issues.

The Senate Report specifically acknowledged the Commission's power ''to determine specifically the parameters of special packaging.'' [10] Additionally, the preamble to FDA's initial test protocol states that ''if experience in application of this protocol indicates a need for change, it may be appropriately amended at that time.'' [11] This is exactly what the rule now issued by the Commission accomplishes.

The PPPA and its legislative history provide further support for CPSC's authority to adopt CR standards that require companies to improve their packages to meet the state of the art. CPSC's packaging standards must be ''technically feasible, practicable, and appropriate . . .'' 15 U.S.C. 1472(a)(2). According to the legislative history, packaging is ''technically feasible'' if ''technology exists to produce packaging conforming to the standard . . . However, *this requirement does not mean that the [Commission] must establish standards that can be met by the lowest, or even the average, level of packaging technology extant in the industry.*''

S. Rep. No. 91–845 at 10 (emphasis added).

And, a standard is ''practicable'' when special packaging for the covered products is adaptable to modern mass production and assembly-line techniques. *Id.* at 10. In addition, Congress made clear that it ''did not desire to limit in any way the development of new forms of special packaging.'' *Id.* at 9.

Thus, CPSC is not required to gear PPPA regulations to the lowest common denominator in the industry. As the state of the art in packaging technology continues to change, so may CPSC's requirements. Industry's argument to the contrary would freeze CR packaging requirements based on the packaging technology that was available 25 years ago. This would require Congress to rewrite the PPPA to account for engineering advances that now allow packages to be both highly child-

[9] The revised protocol adopted by the Commission contains more conditions for participation by adult panelists than does the original protocol. The revised protocol requires that the participants shall: (1) ''Have no obvious or overt physical or mental disability''; (2) have no ''permanent or temporary illness, injury, or disability which would interfere with his/her effective participation''; (3) be able to open and close two types of non-CR packages in a 1-minute screening test; and (4) read and sign a consent form. § 1700.20(a)(3) (i) and (iii). Persons with disqualifying disabilities, whether caused by advanced age or other factors, are disqualified as test participants. This adequately guards against any arguable limitation imposed by section 4 that the panel not consist of elderly people unable to use special packaging.

[10] S. Rep. No. 91–845 at 9 (1970).

[11] 36 FR 22151, 22152. The group that developed the original protocol similarly expected that there would be regulatory changes in the future based upon experience and advances in CR technology. This joint industry-FDA committee was led by Dr. Edward Press, who expected that the standard would ''be improved, revised, [and] expanded within a year or two.'' [295, p. 65] He further foresaw ''that, as new data become available, the [FDA, now the Commission] will establish standards which may differ from those recommended by the [Joint Industry-FDA] Committee.'' [295, p. 111]

resistant and not difficult for normal adults of all ages to open. It is illogical and inconsistent with the statutory framework and its legislative history to think that Congress intended that result.

6. The current rule does not adequately measure difficulty for normal adults; a test using senior adults is better for this purpose. Whatever the boundaries of the category of normal adults (discussed above), the present test with a panel of 18 to 45 year-olds is, at best, a poor measure of whether the packaging is not difficult to use properly. What the test measures is whether, in the 5 minutes allotted time, at least 90% of the panel members can open and, if applicable, properly resecure the packaging. The fact that a person can open a package does not mean that he or she does not find it difficult to do so. Moreover, 5 minutes is probably a much longer time than most adults, even those 18 to 45 years old, will spend attempting to open a package.

The Commission's data show this to be the case. As noted above, from 22 to 64% of persons of ages 18 to 45, depending on package type, found typical CR packaging ''difficult'' to open. [27, 28] No one disputes that, whatever the outer boundaries of the category of ''normal adult'' may be, it surely includes adults of ages 18 to 45 with no overt physical or mental disabilities. Thus, the available data show that much of the currently available CR packaging is difficult for ''normal adults'' to use, even if (as some commenters argued) that term included only the most capable portion of the adult population. Thus, typical CR packaging fails to accomplish the statutory objective, and the Commission is fully justified in changing the test protocol to eliminate difficult-to-use packages from the market.

The present protocol fails to enforce the ''not difficult'' requirement because it tests only whether 90% of the most able half of the population can use packages. The options to address this flaw in the current protocol are few. One alternative would be to survey the adult test participants to see if they found the package not difficult to open. According to the Commission's Human Factors Division, however, this option would make the test less objective and verifiable, and would increase the variability of the results.

The older adult panel retains the ''can use'' criterion that is more objective and verifiable. According to the Commission's Human Factors staff, the ''seniors-able-to-use'' criterion is a reasonable surrogate measure for ''difficulty of use'' in at least a substantial proportion of the population. The requirement for packaging that older adults can use virtually guarantees that CR packaging will not be difficult to use for substantially larger segments of the ''normal'' adult population than in the past, including those 18–45 year-olds who consider traditional CR packaging ''difficult'' to use. Thus, even if people age 50–70 were not ''normal adults'' (and they are), the ability of these older persons to open packaging is a more reasonable surrogate for ''lack of difficulty'' in younger adults than is the present adult test.

As discussed below, the Commission has changed the age range of the adult panel from the proposed 60–75 to 50–70 in the final rule. The Commission continues to believe that it would be lawful to use a panel of 60–75 year-olds. However, the Commission agreed to change the panel because the rule will still save children's lives and, as adopted, reduces the burden of compliance on the regulated industry.

Gender Distribution

A commenter indicated that equal numbers of males and females should be tested, and not the 70% females that was proposed and that is in the current adult test, because children are allegedly exposed equally to products used by males and females. The gender ratio was maintained for the senior test because child care activities are still predominantly performed by females, both in the home and elsewhere. More important, differences in strength between males and females persist in older age groups, and it is appropriate to shift the test sample toward users who represent the lower limits of strength-based performance.

Age Range of Participants

Some commenters claimed that the adult panel should represent the ages of grandparents, who have a mean age of 51 years old. The purpose of the senior test is to provide CRP that can be used without difficulty by a larger portion of the population than packaging that has been available for the past 20 years. The age range for the adult test was not chosen as a representation of the ages of grandparents.

Other commenters requested that the 71–75 year age group be dropped due to variability. Any greater variability of results for people in this age group could be compensated for by allocating a larger portion of the sample to the 71–75 year-old participants and weighting their results so that age group is not overrepresented. However, this point is moot because the Commission decided to adopt a panel of 50–70 year-old adults.

After the most recent comment period, the Commission reexamined its data on tests performed in the 1980's on persons between the ages of 18 and 75. Briefing package, May 25, 1995, Tab G. In those tests, all the packages that scored over 90% with the 61–75 age group also did so with the 51–70 age group. Similarly, all the packages that scored below 90% with the 61–75 age group also did so with the 51–70 group (although one package scored about 85% with the 61–75 age group and just under 90% with the 51–70 age group). Overall, the performance of the 51–70 age group was closer to the 61–75 age group than it was to the 18–45 age group. This was especially so for the packages that older adults found were the hardest to open. For example, the two hardest packages scored 95.3% and 92.5% when tested with the 18–45 group. However, they respectively scored 76.3% and 76.0% with the 61–75 group and 79.8% and 76.8% with the 51–70 group.

These test results indicate that there is a substantial safety benefit associated with using an adult test panel made up of persons of ages 50 to 70, compared to using the present adult test panel of 18–45 year-olds. It is possible that some borderline packages that would fail with the 60–75 age group would pass with the 50–70 age group. However, it is unlikely that this would occur with the hardest-to-open packages that have been marketed previously and that are of the greatest concern to the Commission. The Commission concludes that such hard-to-open packages can be eliminated from the market by a test using either 50–70 year-olds or 60–75 year-olds.

The Commission believes that the required statutory findings—that packaging meeting the standard is technically feasible, practicable, and appropriate for the substances for which it is required—can be made with either a 50–70 year-old panel or a 60–75 year-old panel. However, adopting the 50–70 age range could reduce the burden on industry in complying with the rule. And, the Commission believes that a panel of 50–70 year-olds, like a panel of 60–75 year-olds, will reduce the misuse of CRP. Accordingly, the Commission decided to accommodate industry's requests, and incorporated the 50 to 70 age range for the senior adult test panel in the final rule.

Test Should Reflect the Age of Users of the Product

Several commenters argued that the ages of the test subjects should reflect the ages of the consumers using the

individual products. What these commenters suggested would result in different test populations for different products. None of the products regulated by the PPPA are restricted from being purchased or used by the population in general. Furthermore, the same type of package also is often used for different products. These commenters did not indicate how the ages of the consumers who use the products would be determined, and, if adopted, this suggestion would be a never-ending source of dispute and uncertainty. Thus, the Commission will use the same test population and test procedure to define child-resistance and senior-adult use effectiveness for all regulated products.

Screening Test

Some commenters requested modification of the screening test so that the packages used for screening participants are similar in size, type, and weight to the package being tested. The purpose of the screening test is to ensure that the participating seniors have some baseline ability, including the ability to read, to sign a consent form, and to open two types of non-CR packages. It is unnecessary to change the screening test with each type of package. Therefore, the screening procedures of the senior protocol remain as proposed.

Age Groups

Several commenters requested that the 60–64 and 65–70 age groups be combined to decrease the testing burden. CPSC staff analyses indicate that there was not a significant difference in performance between the 60–64 age group and the 65–70 age group for the package types tested by CPSC, as reported in the March 1994 proposal. [187, 188] This was verified by data submitted by ASTM's Institute for Standards Research (''ISR'') involving senior adult testing of two packages at four different testing agencies. Because there is no significant difference in performance between these two age groups, it is reasonable to reduce the testing burden by combining the two age groups. Therefore, the final rule specifies that sampling be done so that, for each panel, 50 persons are selected for the 60–70 age group.

However, the currently available data do not support the conclusion that adults in the upper and lower ends of the 50–59 age range will perform similarly to one another. Accordingly, as explained in section II(B) of this notice, 25 persons are selected for each of the 50–54 and 55–59 age groups to reduce the practical effects of any lack of homogeneity in the 50–59 age group.

Eliminate Participants Who Stop Trying

Another commenter suggested that participants be eliminated from the test if they stop trying less than 2 minutes into the 5-minute test period. This would introduce a bias towards a package passing by eliminating participants who cannot operate it within 2 minutes and cease trying. The sample of adults would be skewed toward those who are most capable and/or most persistent. This comment was rejected because persons who quit trying in a test situation are likely also to do so in real life. These persons thus probably are the most likely to misuse CRP. Thus, adopting this suggestion could significantly reduce the beneficial effect of the rule.

Number of Tests Per Participant

Several comments were received regarding the number of tests in which a senior may participate. Commenters requested clarification of the CPSC's position on this point. The March 1994 proposal states, in the test instructions for the senior test, ''No adult may participate in more than two tests. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.'' Some commenters requested that the term ''per sitting'' be added to the first sentence of this instruction to avoid an implication that no person could test more than two packages in a lifetime. Another commenter proposed adding the language ''in a 24-hour period'' to the statement.

The purpose of the statement is not to limit testing individuals to two packages per lifetime. The statement in the test instructions is meant to eliminate any effects of continuous testing using the same people, who may tire, gain expertise, or otherwise perform differently after testing several different packages. The term ''per sitting'' does clarify the intent of the restriction and has been added to the adult-test instructions.

One commenter indicated that since adults have had a lifetime of learning how to open CRP, subsequent testing at another time is not a concern. The Commission has concerns about repeated testing by individuals and the potential for abuse. The Commission does not intend that the same participant have multiple ''sittings'' within a short period of time. The Commission does not intend that a panel of people be in effect trained to open packaging.

Neither does the Commission intend that test participants be drawn from a ''pool'' of experienced test participants. There is the potential that people who have failed in the past will not consent to be tested again, thus creating by default a panel of able participants, who bias the test results. This potential exists if testers go frequently to the site where the same people are likely to be found. Although the length of time between testing needed to ensure that these sorts of problems do not occur is unknown, the Commission recommends against testing at sites containing a defined group more than 3 to 4 times a year.

The potential for abuse could be partially eliminated by specifying a time period between testing the same individual. However, it is difficult to identify the proper length of time between tests. In addition, it would be impossible to measure compliance with such a requirement, unless participant data bases and reporting were also required. It was also suggested that the participant, rather than the test agency, be responsible for the frequency of testing. It was suggested that this could be done by including a statement on the consent form, such as ''I am between the ages of 50 and 70 and, to the best of my knowledge, I have not tested a child-resistant package within (insert a time).'' This would place an additional and unnecessary burden on the participants. Also, there are no data showing that participants would have a sufficient recollection of the time since they were last tested to make this a practical way to deal with the problem.

Sites

Several comments were received regarding the sites used for testing. The proposed rule states that no more than 24% of adults should be tested at any one site. This would require that a minimum of five sites be used. Commenters requested that the number of sites required be lowered to four.

In the March 1994 proposal, the Commission analyzed the sites grouped together by geographic area (3 digit zip code), not by the zip code of the participants, as many of the commenters stated. [187, 188] The sites were grouped together geographically because there were inadequate numbers of participants tested at each site for any meaningful analysis of site variability. This geographic analysis showed that there was no variability among the groups of sites in CPSC's tests, which all used the five-site minimum. There are no test data on the effect on test results of decreasing the required number of sites. Accordingly, there is no basis for

reducing the number of required sites from five to four.

Another commenter suggested that the definition of site be changed from a location to a group of panelists at a specific location under a group name. The commenter stated that test results could differ dramatically between different groups of people based on the characteristics of a group and not the actual location of the group. This comment would allow testing at only one geographic site if a sufficient number of different groups were tested.

Defining a site as a group of people would limit testing to defined groups, such as a bridge club or a senior citizens meeting on a particular day. This would eliminate sampling from a mall or other area where people are not congregated for a central purpose. There is no information on how this change would affect test results. The Commission concludes that by selecting a variety of geographic sites there is a likelihood that senior adults will be selected with diverse interests and backgrounds.

Another commenter requested that central location testing be permitted as long as adults were not drawn from the same geographic area. This commenter submitted data indicating that selecting senior adults from large central locations, such as shopping malls, can result in geographic diversity, as measured using residential zip codes. CPSC staff agrees that large central locations can provide geographic diversity in the selection of subjects, and that this type of diversity is desirable. However, there is no information on whether the use of large central locations has an effect on actual test data. Factors other than geographic diversity may be important. By selecting a variety of sites, there is a likelihood that senior adults are selected with diverse interests and diverse backgrounds. Therefore, the Commission concludes that senior testing should continue with the requirement of a minimum of five test sites. However, the Commission's consent forms are being amended to collect information about participant's residential zip code, so this suggestion can be evaluated in the future.

Sequential Test

Several comments were received about the proposed sequential test and about its alleged effects on the standards for passing the senior test. Several commenters complained that the CPSC increased the stringency of the test since, with the sequential adult test, a SAUE of 0.951 would have been required to pass after testing the first panel of 100 seniors. The proposed sequential test would not have increased the test's stringency, however, since the pass/fail criterion would have remained 0.900.

The main advantage of a sequential test would be to increase the probability of making the correct pass/fail decision for those packages that perform in the ''borderline'' (near 0.900) range. This is accomplished by increasing the number of people tested for borderline packages. Thus, the sequential test would have required testing more adults for packages that perform near the 0.900 pass/fail criterion.

However, borderline packages are not the hardest-to-open packages that are of the greatest concern to the Commission. The Commission believes that the hardest packages to use will be eliminated by a panel of 50–70 year-olds, even without a sequential test.

Therefore, the Commission believes that it can use nonsequential testing, which may reduce the burden on industry, without compromising the safety benefits of the rule. Accordingly, both the senior- and younger-adult tests will use a single 100-member panel.

Senior Consent Forms

Several commenters requested that the actual language of the adult consent form be included in the rule to further standardize the test. It was also requested that different forms be used for reclosable and non-reclosable packages, that participants be told about the time limits of the test, and that participants be informed that they may be asked to open other types of packages (i.e., those used for screening purposes).

The Commission agrees that the consent form should be standardized; the consent forms used in Commission testing are now included in the rule as a recommended example. In current testing, separate forms are used for reclosable and non-reclosable packages. In addition, language about the potential to be asked to test screening packages has been added to the consent form.

However, the Commission disagrees that participants should be advised of the time limits of the test (e.g., ''you have 1 minute''). Time pressure is a potentially influential factor, and emphasizing a time limit may induce anxiety unnecessarily among participants.

Instructions

Comments were received that the sample preparation sections of the child test and the senior test were not consistent. The Commission agrees and has modified § 1700.20(a)(3)(iv)(A) of the senior test.

Several requests for further standardization of the instructions were received. Commenters requested standardization of the commands to participants in the screening test to reflect what is said in the regular test. Some commenters also indicated that standardized language should be added to the procedure to help confirm whether a participant has given up. The Commission agrees with these changes and has amended the test procedure in § 1700.20 to include additional standardized language.

E. Effectiveness of the Senior Protocol—Safety v. Convenience

A number of commenters attacked the basic premise of the revisions, that easier-to-open packages will result in increased proper use of CRP by adults and that this will increase the safety of children. Some commenters cast this argument as follows: If (as the commenters contended) the rule does not increase safety, it perforce addresses only convenience and is not a proper subject for a Commission regulation.[12] However, the information in the record indicates that the senior-friendly adult test will have significant safety benefits and will not compromise child-resistance.

The Rule Will Cause Beneficial Changes in Adult Behavior

Large numbers of adults are currently relegated to using non-CR packages because of the difficulty in using traditional CR packages. For example, CPSC test results show that up to 44% of 61–75 year old adults could not open CR packages that pass the current protocol. [37] However, under the revised protocol, these adults will be able to use CR packaging and thereby reduce the risk of accidental poisonings.

The likelihood that people will defeat a safety measure through error, misuse, or avoidance increases with the degree of actual or perceived effort and inconvenience required to use the measure. [234, 287] This is evidenced by the current problems with CRP, i.e., difficult-to-use containers often are used improperly or not at all. Conversely, research findings indicate that when the degree of effort or inconvenience associated with safe behavior is reduced, the likelihood of compliance increases. [287]

The protocol revisions directly address the capability of the general population to use a given type of CR package by requiring that at least 90%

[12] Given that the Coalition for Responsible Packaging, which represents the proponents of this argument, now endorses the rule as adopted [299], it appears that these claims no longer apply.

of test participants of ages 50 to 70 be able to use them. Recent test results with older adults showed that 95% to 99% of the 60 to 75 year-olds sampled were able to use the newer types of reclosable packages tested. [195] Furthermore, the majority of participants rated the packages ''easy to use.'' [195] Similar results were obtained for non-reclosable packaging. [194] These results would almost certainly hold or be even stronger for the 50–60 age group.

The Commission concludes that packaging that older adults can use, and which they perceive to be easy to use, has a higher likelihood of being used correctly by the general population than packaging they cannot use, or which they perceive to be difficult to use.

The Revised Protocols Will Not Compromise Child Safety

Several commenters argued that the proposed changes will lead to a reduction in child-resistance. Their argument is that packages that currently pass at, e.g., 95% CR effectiveness may be replaced with packages that pass at a lower effectiveness after the revised protocols are adopted. However, the Commission's tests of senior-friendly packages have shown that packages which are easier for senior adults to open need not be easier for children to open. Child-resistance effectiveness levels with the reclosable senior-friendly packages tested by CPSC varied from 97% to 100%, which are as child-resistant as the most effective of traditional CR packaging. [195]

One commenter submitted graphs depicting test data purportedly showing that modifications to CR packaging to make them more adult accessible result in less child-resistance. [275, 278] The commenter did not identify the packages tested, describe in detail the changes that were made to the packages, or provide the raw data for the tests. Indeed, for two of the five graphs purporting to reflect industry testing, no backup information was presented. The Commission cannot determine for any of the graphs whether the appropriate protocol was adequately followed or whether the effectiveness scores were calculated properly.[13] The failure to provide these data makes it impossible to make a thorough or meaningful assessment of this commenter's submission.

Moreover, two of the five packages in these graphs purportedly scored at least 96% in both the child and adult tests. Thus, the limited information supplied by this commenter shows, at most, that some packages may need further modification or may need to be replaced with commercially available packages having both high adult-effectiveness and high child-resistance.

Another argument raised by these commenters was that each percentage point of reduction in true child-resistance would result in a potential 32 million product failures. This figure apparently was obtained by dividing 100 into the estimated 3.2 billion CR packages produced each year. This argument overlooks the fact that even a package for which child-resistance has been slightly reduced to make it easier for adults to open will still be far more child-resistant than one where the cap has been left off or loose because it was difficult to open. A package that is not child-resistant or that is misused is less than 9% child-resistant, versus at least 80% child-resistant for packages that pass the protocol.[14] Thus, each additional unit that is purchased in CR packaging and used properly because it is less difficult for adults to use can be over 10 times more child-resistant than non-CR packaging or misused CR packaging.

The Commission is unable to quantify the number of poisonings that will be prevented by the new rule, and such a calculation is not statutorily required. However, the record evidence—including survey data, human factors analysis, and other information—indicates that this rule will increase the proper use of CR packaging, reduce injuries, and save children's lives.

One commenter argued that persons who start using CR packaging because it is easier to open may let their guard down and not be as vigilant about keeping the products out of the reach of children. The commenter claimed that this will result in increased poisonings. However, it is speculative whether caregivers will likely get a false sense of security if they switch from non-CR packaging to CR packaging. And, the Commission is not aware of any evidence that this occurred when CR packages were first introduced.

Because no CR packaging is childproof, it will always be important to endeavor to keep hazardous products out of the reach of children. Although it may well still be important to educate people about the need to keep hazardous products away from children, the rationale for the PPPA is that education alone is inadequate to address the problem of accidental childhood poisonings:

> Efforts at public education are based on the premise that poisonings are caused by parental negligence and that poisonings can be prevented by stimulation of greater parental care. The Committee, however, believes that parental negligence is not the primary cause of poisonings. There are too many potentially hazardous products in the modern home to hope that all of them can be kept out of the reach of children. Special packaging will accomplish what previous efforts have not b[y] attempting to create positive separation between young children and hazardous substances. Special packaging is intended simply to make the environment of young children safer.
>
> S. Rep. No. 91–845 at 3.

Finally, the Commission has addressed through discretionary enforcement stays the possibility that a manufacturer may have difficulty maintaining the child-resistance of packaging while complying with the new protocol. Specifically, as discussed below, one of the grounds for such stays is that more time is needed to develop CRP that will meet the new protocol and not significantly reduce the child-resistance of the package.

The Commission May Issue Safety Rules That Improve Convenience

One commenter also argued that the Commission could not issue the proposed rule because an ease-of-use regulation, even if it had a safety rationale, would not be a ''safety standard'' under the Consumer Product Safety Act (''CPSA''). As an example, the commenter claimed that the Commission could not use the CPSA to issue a convenience standard for lawn mowers.

The fact that the PPPA contains a specific ease-of-use requirement (that the packaging be not difficult for normal adults) is sufficient to refute this contention, regardless of what might be done under the CPSA. As regards the example of lawn mowers, however, the Commission's Safety Standard for Walk-Behind Power Lawn Mowers (issued under the CPSA), actually does contain a safety provision linked to convenience. See 16 CFR 1205.5(a)(iv). Thus, even under the CPSA, the Commission may issue standards fashioned to ensure safe behavior by consumers, even if that standard addresses the ''convenience'' of a safety feature.

Market Forces Have Failed To Eliminate Difficult-To-Use Packaging

Finally, a number of commenters argued that ease of use would be best

[13] The Commission previously received another industry comment in which the SAUE scores were all calculated incorrectly, assuming the age group proportions were correct.

[14] Wilbur, C.J., ''Closure Testing Equipment Studies, Status Reports, Non-Child Resistant, Snap Type Packaging and Continuous Threaded Type Packaging, CPSC,'' CPSC Directorate for Health Sciences (March 1990).

addressed by market forces. However, in the 20-plus years the PPPA has been in effect, there has been only minimal market penetration by packages thought to meet the new protocol.

At the presentation of oral comments, a commenter argued that it would be different in the future now that senior-friendly packaging that is highly child-resistant has been introduced to the market. He explained that as soon as other companies developed such packaging, they would be forced by competitive forces to use it. The commenter presented no data or evidence to support this optimistic scenario.

There is no reason to believe that, in this case, large segments of the market will make needed safety changes unless such changes are mandatory. For the most part, industry has shown no willingness to spend money and time voluntarily to make significant improvements in the performance of CR packages. Consumers may not even realize that easy-to-use packaging can be produced. Also, consumers can purchase packaging without a CR feature, and consumers have ''solved'' the problem of difficult packaging by leaving caps off or loose or putting the contents in another container.

Many packaging manufacturers are apparently reluctant to make a substantial capital investment to produce easier to open packaging that will then have to compete with established lines. As a CR package manufacturer stated in commenting on the proposed rule:

> [A]s long as we don't encourage manufacturers to produce good, effective child-resistant closures, they will never get around to doing it. And as long as we continue to allow these so-called child resistant products that require force or tools to be acceptable, no one can get on the market with a good child-resistant closure. It would be foolish for any individual or company to invest millions of dollars when that type of competition is present and allowed.
>
> [Comment CP1–91–1]

Indeed, at the oral hearing, another commenter stated that interest in a new aerosol package he is developing decreased by 50% over the 2 months since the Commission had excluded aerosol packages from the rule. [273, p. 104]

In short, there is no basis in the record to conclude that market forces will ensure the adoption of senior-friendly CR packaging.

Education

One commenter stated that a carefully designed and executed education program has the potential to reduce childhood poisonings far more than changing the test protocol for CRP. Other commenters concluded that the problem is one of adult responsibility; they contend that education of the senior population is as important as, or more important than, package changes.

The Commission agrees that education efforts will be a necessary concomitant to the revised standards to publicize the availability of easy-to-use packaging and to remind people about the importance of keeping hazardous products out of the reach of children. However, education is unlikely to solve this problem as effectively as changes in available packages. As noted above, in adopting the PPPA, Congress recognized that education alone could not solve the problem of accidental poisonings of children. S. Rep. No. 91–845 at 3. Certainly, education alone cannot address the issue of adult responsibility for the adults who cannot use some of the CRP currently on the market. Participation by the industry in this type of education campaign is welcomed by the Commission.

F. ISR Testing

The Institute for Standards Research (''ISR''), a subsidiary of the ASTM, sponsored tests to measure the interlaboratory variability expected when conducting CR package tests according to the proposed protocols. The ISR testing program involved testing two package types, ASTM Type IIA (lug) and Type VIIID (blister), by four different testing agencies. Four senior panels were run at each agency for each package.

Both the ISR and the ISR project manager commented on the results of the ISR testing and on the comparison of the ISR results with those obtained from CPSC-sponsored testing conducted by a single testing agency. [210, Refs. 17 and 35]

In the CPSC-sponsored testing of each of these two package types, a pass determination was made within the first three test panels, regardless of the order in which the panels were considered, indicating that the probability of these packages ever failing was very low. [187] The same results were obtained in the ISR-sponsored testing. Additionally, no package tested in either CPSC-sponsored or ISR-sponsored testing had a calculated effectiveness below 90% for any test panel, indicating that no package was ever close to failing the senior adult test. [187, 230]

The ISR noted that there was a statistically significant difference in the senior-adult use effectiveness among agencies for the lug package. [210, Ref. 17] A high pass rate for the lug package at one testing agency was responsible for this conclusion. [230] The reason for this difference is unknown. It may be because the ISR study was not standardized sufficiently at the various testing agencies, so that the study was conducted differently at one testing agency from the way it was conducted at the other testing agencies. [230] Since CPSC staff did not observe the actual testing, there is no way for the Commission to determine if this was the case. In any event, however, the results of the ISR-sponsored testing verified the proposed CPSC test method.

G. Household Chemicals

Several commenters requested that household chemical products be regulated separately from pharmaceutical products. Commenters argued that household chemical products should be excluded from the proposed test method because the CPSC allegedly has not demonstrated a significant rate of serious personal injury or illness from poisoning incidents where CR closures were left off household products by the elderly. Commenters also claimed that the Commission inappropriately generalized NEISS data pertaining to injuries to children in the pharmaceutical category to all regulated household products within its jurisdiction, including chemical specialty products.

These commenters are referring to a study conducted from NEISS cases that investigated poisonings from only pharmaceutical products. [112] While the Commission has no comparable data on household chemicals, the Commission is aware of ingestions and deaths of children from PPPA-regulated household products. Household chemicals regulated under the PPPA include oven cleaners, furniture polish, turpentine, kindling and illumination preparations, ethylene glycol, solvents for paint or other similar surface-coating materials, glue removers containing acetonitrile, and permanent wave neutralizers containing sodium bromate or potassium bromate. The CPSC staff monitors ingestions and deaths from these products. (If cleaning products are registered pesticides, they are regulated by the Environmental Protection Agency and not the CPSC.)

Many specialty cleaning products are toxic following ingestion. One published article calculates hazard factors for household products through an analysis of data from the American Association of Poison Control Centers (AAPCC) pertaining to reported exposures of children under 6 years of

age. [230, Ref. 6] A hazard factor was derived from the number of serious exposures for a substance, normalized to the overall rate of major effects and deaths.

Hazard factors for many of these products, including acid and alkali drain cleaners, alkali oven cleaners, and ethylene-glycol-based products, were found to be significantly higher than the hazard factor for all other reported cases, despite the fact that CRP is already required for these substances. Thus, children are exposed to these toxic household chemicals.

It is expected that CRP capable of passing the senior adult test will be easier for adults to use correctly, and the availability of such packaging will encourage adults to purchase the products in CRP and properly use the packaging. It seems particularly important to make such a requirement for these household products, because data submitted by one commenter showed low senior-adult test scores for household chemical products. Senior test data submitted by this commenter for 12 different packages showed that 10 packages had senior effectiveness below 90%. Two packages had senior-effectiveness below 50%. [210, Ref. 15] Since many of the household chemical products are quite toxic, it is reasonable to require that such products be in CRP that adults are capable of opening and resecuring properly.

The majority of packaging for household chemicals (approximately 65%) uses the same CRP types used for pharmaceutical products. [233] For these products, it is just as feasible to provide improved CRP for household products as it is for pharmaceutical products. For the remaining household products, primarily products in metal cans or aerosol dispensers, there are no test data demonstrating that currently commercially available packages are senior-friendly.

Senior-friendly packaging may be developed for metal cans, especially if the cap is designed for the use of a tool to aid in opening. A tool is especially useful for this application since the caps for products in metal cans often are applied initially with a high torque to prevent leakage during shipment. After the initial opening, the option for a tool is available if needed. The Commission is aware of one promising prototype of a cap for metal cans that has senior-friendliness as a design goal. [213, 245, 251] Any applications that use both a metal can and a metal closure would probably take the longest to develop and implement senior-friendly packaging. [232, 240]

As to aerosols, various types of senior-friendly overcaps show promise. [232, 240] In addition, designs that use a tool to remove an overcap may be developed. [170, 183, 232 Ref. 15, 240 Ref. 11, 248] There is an existing design that places the aerosol actuating button in a narrow recess that is deep enough that the button can be reached by an adult's finger, but not by a child's. [240 Ref. 12, 261] Another design uses an annular ring that is mounted around the aerosol can so that it can rotate but is not removable. [256] The overcap screws into the upper portion of the rotatable ring. If one holds the body of the can and tries to unscrew the overcap, the ring rotates and the overcap will not unscrew. To remove the overcap, the ring must be held so it does not rotate while the cap is being unscrewed. Although both of these designs are promising, the Commission does not know whether they have been subjected to either the child or senior-adult tests.

The Commission concludes that there are currently a substantial number of ingestions by children of household chemicals and that a significant portion of seniors cannot open and resecure existing packages. Thus, improving the packages will reduce the likelihood that the CR package will be defeated or not resecured. Therefore, the Commission decided to include household chemicals as a group in the requirement for senior-friendly packaging.

Nevertheless, as noted above, aerosols and metal packages with metal closures are likely to take the longest time to implement senior-friendly packaging, and to present the most difficulties. Excluding these two types of packaging from the revised requirements at this time will also reduce the potential competition for the services of testing organizations during the 30-month period before compliance with the revised adult test will be required for other products.

The Commission's technical staff believes that senior-friendly packaging for all products, including those in metal containers and in aerosols, can be produced eventually. Nevertheless, excluding products that require metal or aerosol containers from the revised requirements will enable the Commission to monitor the further development and testing of these limited types of packaging before making any subsequent decision about whether or not to require such packages to be senior-friendly.

Accordingly, the Commission concludes that products that must be packaged in metal packages with metal closures, or in aerosols, will not be subject to the senior-adult test that is issued below. However, the Commission will monitor the development of senior-friendly versions of these types of packages and revisit this issue at a later time. These metal and aerosol containers will be subject to the revised child test and will remain subject to the current younger-adult test. All other products presently subject to special packaging requirements under the PPPA will be subject to the revised child and senior-adult requirements.

A product will be deemed to require metal containers or aerosol form if:

1. No other packaging type would comply with other state or Federal regulations,
2. No other packaging can reasonably be used for the product's intended application,
3. No other packaging or closure material would be compatible with the substance,
4. No other suitable packaging type would provide adequate shelf-life for the product's intended use, or
5. Any other reason clearly demonstrates that such packaging is required.

In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product, or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure. If requested by the Commission's staff, the manufacturer or packager of a product packaged in a non-senior-friendly metal or aerosol container will provide a justification of why, under the criteria specified above, the product requires such packaging.

H. Comments on Statutory Findings

Many commenters claimed that the Commission did not have sufficient information to make the statutory findings that technically feasible, practicable, and appropriate senior-friendly CRP is available for all substances regulated under the PPPA.

Some commenters seem to believe that in order for a package to be technically feasible, practicable, and appropriate, it must be commercially available. This is not the case. These findings mean that senior-friendly CR packages can be made and mass produced that are compatible with the substances to be packaged. The CPSC presented data in the March 1994 **Federal Register** notice on many different packages that are commercially available and have passed the senior-friendly protocol. In addition, closure manufacturers have indicated that other types of senior-friendly packaging can

be developed. Manufacturers and packagers may also consider alternative packaging. The lack of commercial availability of a closure for a particular specialty package does not mean that a closure cannot be developed for that package or that other packages would be inappropriate for the product. A detailed discussion of the Commission's findings is in section V of this notice.

I. 1-Year Effective Date, Blanket 18-Month Exemption from Compliance, and Additional Temporary Stays of Enforcement

In the October 5, 1990, **Federal Register** notice, the Commission proposed 1 year after promulgation as the effective date for the proposed senior-adult test. This is the longest effective date authorized in the PPPA. The Commission requested information about the economic effect of the effective date.

Alternatives to a 1-Year Effective Date

Commenters voiced concern about the limited availability of testing firms and senior-friendly packaging in the proposed 1-year period. The commenters suggested alternative approaches, including grandfathering existing CRP, phasing-in by product class, phasing-in by package type, and corporate averaging. Commenters also requested the formation of a CRP conversion task force for determining appropriate effective dates. Another commenter requested that the Commission issue a compliance policy guide.

1. Grandfathering existing CRP. If adopted, this comment could negate the objective of the regulation, which is to ensure that currently marketed hard-to-open CRP is removed from the market. The objective of grandfathering for a limited period of time is achieved by the 18-month blanket exemption from compliance being provided by the Commission. This is discussed in more detail below.

2. Limited testing facilities. Commenters argued that there is insufficient capacity for testing CRP to enable all products to be tested in time to comply with a 1-year effective date. Although the current capacity of testing organizations may be insufficient to provide enough tests of CRP to ensure that all products can be tested and senior-friendly packaging implemented within 1 year, these firms do plan to increase their capacity as much as possible to take advantage of the increase in demand for their services.

In addition, the revised procedures are specified in enough detail that some manufacturers and packagers could conduct their own tests for compliance with the revised protocol. This was shown by the ISR tests, which used one laboratory that had no previous experience in conducting CR package tests. Also, it is expected that additional testing laboratories will form to meet this need. The CPSC's staff has had many inquiries from marketing groups and universities interested in providing testing services.

The Commission's 18-month exemption from compliance, discussed below, also will accommodate delays caused by any lack of appropriate test facilities.

3. Phase-in by product class. Many commenters suggested that the revised requirements be phased in by product class. Various suggestions were made as to which product classes should go first.

The Commission does not agree that this phase-in approach is an efficient way to obtain the most complying CRP in a short but reasonable time. In most product categories, some packaging has been developed that will comply with the revised protocol. Thus, regulating by product class would have given many companies more time to comply than is necessary.

4. Phase-in by package type. Another option suggested for a phase-in approach was to phase in by package types. The Commission did not adopt this approach, because it could have unnecessarily delayed use of senior-friendly packaging. If a package design truly presents unusual problems in complying, the procedure for temporary stays of enforcement can be used.

5. Corporate averaging. One commenter stated that corporate averaging would be an appropriate system for phasing in the effective date. A specified percentage of a company's products would have to comply with the new regulations by a specified time, and the rest of its products would be phased in by percentage over time.

The Commission does not believe this would be an efficient way to implement the regulation. Many companies use only one type of packaging, and additional time is not necessary. Also, the Commission would be unable to monitor compliance with the regulation since the CPSC would not know what particular products or packages should comply. Even if industry undertook to keep the Commission fully advised, the burden on both industry and the Commission would be enormous.

6. Task force. One commenter suggested that a task force, consisting of CPSC staff, industry, closure suppliers, and testing agencies, determine compliance time frames. The Commission rejected this approach as impractical and unnecessary. No procedure was described to resolve disagreements on such a task force or to insure that the public interest would be adequately represented. Furthermore, there is no mechanism to enforce the determinations of a task force except the time-consuming one of additional rulemaking proceedings by the Commission.

7. Compliance policy guide. One commenter requested that the Commission issue a compliance policy guide (''CPG'') concerning its enforcement of the new standards. The commenter suggests that the Commission develop a policy statement which establishes criteria by which a manufacturer would be considered to have demonstrated a good faith effort to comply with the standards. CPSC then would not take action against packaging not meeting the standards if the manufacturer had satisfied the criteria specified in the policy.

This CPG approach is less practical than the procedure for an 18-month compliance exemption. Rather than trying to anticipate all the possible ways in which a good faith effort could be thwarted, it will be much more efficient to deal with such situations through a time-limited exemption, followed by additional individual temporary enforcement stays, where justified.

None of the approaches suggested by the commenters provides an efficient method to obtain the largest amount of senior-friendly packaging on the market in the shortest reasonable time. The Commission estimates that most products subject to the requirements could comply within 1 year. However, as discussed below, an 18-month compliance exemption is established to address many of the cost factors involved in a 1-year effective date.

8. Exemption from compliance. The PPPA requires that the effective date of a regulation establishing a special packaging standard shall not be later than 1 year after the date that the regulation is final (*i.e.*, is published in the **Federal Register** as a final rule). Having found that designs of child-resistant packaging that meet the requirements of the revised testing protocol are technically feasible, practicable, and appropriate, the Commission has allowed the statutory maximum one year for the revisions to the testing protocol to go into effect. Data available to the Commission indicate that sufficient quantities of these designs could be manufactured within a year to meet the demand for packages that comply with the revised testing requirements.

The Commission recognizes that the revised standard may affect as many as 3 billion packages annually. This will require action on the part of closure manufacturers, as well as packagers of products subject to regulations, manufacturers of bottles and containers, mold manufacturers, and other firms involved in the packaging and distribution of products subject to PPPA regulations. In adopting these protocol revisions, the Commission wants to (i) minimize any commercial disruption, (ii) allow for a more orderly transition to packaging that complies with the revised requirements, and (iii) help assure that—consistent with the results of CPSC testing on certain currently available packages—any other new packaging designs or modifications provide ease of adult use without sacrificing child resistance. Therefore, the Commission is granting companies a blanket exemption from having to comply with the revised adult protocol for 18 months after it goes into effect. The exemption from the senior-adult requirement will apply only to products that comply with the younger-adult requirement.

The Commission believes that the additional 18 months will provide adequate time for affected firms to make any necessary changes to their packages or machinery, and to place orders for complying packaging in a timely manner that assures delivery well in advance of the effective date. The Commission also recognizes, however, that unique circumstances may arise that require additional time for individual firms to comply. The Commission will therefore also consider requests for additional reasonable enforcement stays after the expiration of the 18-month exemption.

The Commission, through appropriate staff, shall grant a request for an enforcement stay that demonstrates, based upon supporting information and documentation, (i) a good-faith effort to obtain packaging that complies with the revised standards during the period after publication of the final rule in the **Federal Register**, and (ii) compliance with one of the following criteria:

1. *Delay in Protocol Testing.* Protocol testing likely will not be completed within the time required to enable complying packages to be used by the applicable deadline. Estimated dates upon which testing will be completed and complying products will be produced shall be submitted. (Several protocol testing firms should be contacted to obtain the earliest completion date.)

2. *Product Testing.* Required FDA testing likely will not be completed within the time required to enable complying packages to be used by the applicable deadline. Estimated dates by which testing will be completed and complying products will be produced shall be submitted.

3. *Equipment.* Necessary manufacturing equipment will likely not be available within the time required to manufacture finished products in compliance with the revised requirements. The estimated date by which equipment will be in use and complying CRP will be produced shall be submitted.

4. *CRP Availability.* Where CRP is claimed to be unavailable, an explanation shall be provided of why currently available, alternative CRP cannot reasonably or practicably be used. An estimated date by which complying CRP will be obtained and produced shall also be submitted.

5. *Redesigned/New CRP: Maintaining Child Resistance.* Where a claim is made that CRP will have to be redesigned or developed, an explanation shall be provided of why commercially available packaging cannot reasonably or practicably be used. The rationale for a temporary enforcement stay under this provision may include, among other reasons, that more time is reasonably needed to develop a CRP that will meet the new adult protocol and not significantly reduce the child resistance of the package. An estimated date by which complying CRP will be obtained and produced shall also be submitted.

6. *Other.* Other substantial reasons demonstrating that additional time is reasonably necessary to comply with the amended protocol. An estimated date by which complying CRP will be obtained and implemented shall be submitted.

The Commission, through appropriate staff, shall issue a decision granting or denying the request for a temporary stay of enforcement within 30 days after receipt of the request and appropriate supporting material. All requests for enforcement stays, including any supporting data or information, for which claims of confidentiality are made, shall be considered confidential and exempt from public disclosure to the extent allowable by law.

J. Miscellaneous Comments

Carpal Tunnel Syndrome

Comments were received by groups representing pharmacists that requested that the Commission and manufacturers consider the need for a design of CRP that reduces the incidence of repetitive motion injuries, such as carpal tunnel syndrome, among pharmacists. Letters were received from pharmacists with carpal tunnel syndrome.

Carpal tunnel syndrome is caused by compression of the nerves in the wrist. It is associated with occupations that require repeated forceful wrist bending. Some of the pharmacists attribute their repetitive motion injuries to opening and closing certain designs of CRP.

The CPSC is prohibited by the PPPA from prescribing specific package designs, and the Commission is unaware of any performance test for CRP that would have the effect of reducing carpal tunnel syndrome. However, packages that are easier for seniors to use should be easier for everyone, including pharmacists, to use. The effect this will have on the development of carpal tunnel syndrome in pharmacists is unknown.

Exemption for Large-Diameter Packages

One commenter, a manufacturer of swimming pool chemicals, requested that large diameter packages, over 110 mm, be exempted from the senior test. The manufacturer provided test data on the packaging used currently by the firm. In all cases, the packages failed the proposed senior test.

It should be noted that this specific manufacturer makes products regulated by the Environmental Protection Agency (EPA) and not by the CPSC. The decision on whether to exempt this product thus will be the EPA's responsibility.

In general, however, the Commission does not believe that failing data on existing packages is reason enough for a permanent exemption from the revised protocol. The Commission believes that senior-friendly CRP for all CPSC-regulated products is technically feasible, practicable, and appropriate. Removing existing CRP from the market that cannot be used properly by the senior panel is the purpose of the revisions.

Need for Additional Comment

After the Commission voted to issue the revised protocol containing the older-adult test panel of 50–70 year-olds, an individual wrote to the Commission suggesting that the changes from the proposal should have been published so that those particular changes could be commented on by the public. The Commission does not believe such action is either legally required or sound policy. All the changes from the proposal are within the range of issues discussed in earlier **Federal Register** notices. Furthermore, the final rule is a logical outgrowth of the previous notices and the comments received in the rulemaking. Thus, an additional opportunity for public comment is not required and would significantly delay the substantial safety benefits of the rule.

IV. Economic Issues [236]

A. General

More than 20 categories of substances require special packaging.[15] These include oral prescription drugs; aspirin, acetaminophen, ibuprofen, and

[15] The substances are specified at 16 CFR 1700.14.

loperamide in OTC drugs; potassium and sodium bromates in permanent wave neutralizers; low-viscosity mineral seal oil and/or other petroleum distillates in furniture polish; and turpentine, sodium and/or potassium hydroxide, methyl alcohol, sulfuric acid and ethylene glycol in various household products. Product formulations include liquids, gels, solids, flakes, granules, and powders.

Oral liquid pharmaceuticals are either prepackaged by the manufacturer or pharmacy-dispensed using reclosable continuous-threaded (''CT'') closures. Some liquids are available in non-reclosable unit-dose packages. Most oral solid dosages (tablets and capsules) are either prepackaged in plastic bottles with CT or snap closures or are pharmacy-dispensed in vials with CR lug-finish closures. However, the number of solid dosage preparations that are prepackaged by the manufacturer in non-reclosable blisters or pouches is growing, according to an industry study from Leading Edge Reports.[16]

Household products are supplied in a greater variety of container shapes and in larger volume sizes than are drug preparations. According to commenters, approximately 65% of household products use styles similar or identical to those used for drug products. [233] CRP for household products include plastic, glass, fiberboard, and metal containers with plastic, metal, or combination metal/plastic closures or dispensers. CR closure styles include CT, overcap, and various specialty designs unique to a particular product/container. Some household products are supplied in single-use non-reclosable pouches or bags. Larger packages (5 gallons or more) of household substances are not required to meet special packaging requirements. (16 CFR 1701.3)[17]

Closures are seals or lids, typically made of plastic or metal. The closure and the container together make a package. Plastic CR closures (SIC 3089) make up only a small portion of the total closure market (CRP and non-CRP).[18] In 1991, 73 firms shipped 39.2 billion closures, of which only 3.0 billion units (8%) were CR. Prescription drugs accounted for 29% (0.9 billion) of CR closures, while the remaining 71% (2.1 billion) were used on ''All Other,'' a category that includes OTC drugs. Census data do not provide a breakout for OTC drugs and other products.

According to the Census Bureau, 14 of the 73 closure manufacturers ship CR closures for prescription drugs and 26 of the 73 ship CR closures for all other products. It is likely that the 14 manufacturers of CR closures for prescription drugs also manufacture CR closures for other regulated products (i.e., are a subset of the 26 other CR closure manufacturers). It is likely, too, that a substantial number of the CR closure manufacturers also produce non-CR closures and numerous other plastic products. Industry spokespersons estimate that the four largest manufacturers of plastic closures account for over 80% of the CR closure market.

Metal and metal composite closures are also available for use on products requiring CRP. However, they comprise an even smaller part of the market than plastic closures. The companies producing them are classified in SIC 3466, Crown and Closures. In 1991, 27 companies shipped an estimated 17.5 billion metal and metal composite closures. About 0.5 billion units (3%) were manufactured by 10 companies and used on medicine packages. Census data do not provide a breakout by use for CR metal closures.

Firms involved in providing the materials for non-reclosable packages (e.g., films, foils, and adhesive-coated paperboard backings) are a diverse group of suppliers of packaging materials and equipment. Their products are used by pharmaceutical and household product manufacturers for non-reclosable packages such as blister configurations and pouches that are fabricated at the time they are filled. Packages can readily be fabricated as CR or non-CR, depending upon the characteristics of the materials used.

The revised protocol will likely cause many changes in the packaging of products subject to the PPPA. The changes are both expected and desirable, since the widespread availability and use of senior-friendly packaging will help to minimize the number of accidental poisonings of young children. In the short run, however, achieving a more senior-friendly universe of CRP also will entail costs or other effects to industry. The Final Regulatory Flexibility Analysis in section VIII of this notice includes more detail regarding impacts on small entities. There are also effects on consumers.

In general, most firms should be able to comply with the revised rule with modest cost effects on themselves or their customers, because complying closures are known to exist and to be available at low incremental costs. However, there are several categories of effects of the revised PPPA protocols, especially where firms undertake to develop new or modified packaging. These effects include: design and development of new or modified closures; testing to determine compliance with the CR protocol requirements and, if needed, the requirements of other agencies; testing to ensure product integrity or to meet other standards, such as strength or stability; testing for consumer acceptance, if desired; modification of packaging equipment to accommodate the new packaging; production costs; and other miscellaneous effects. Production costs, which would be ongoing, will not be significant. The remaining costs are one-time, up-front expenditures.

B. Economic Comments

Many commenters expressed concern that the revised regulations will result in increased costs in several areas. The response to specific comments is presented below.

Test costs. Some commenters claimed that the cost of testing will increase because of the requirement of informed consent for the child test and the increased numbers of seniors tested in the sequential senior test.

As was discussed previously, the CPSC is required to use informed consent in all human testing. However, data obtained from child tests conducted without informed consent will not be disregarded based on the lack of informed consent alone. Since there is no requirement for testing, it is the package or product manufacturer's decision to test either with or without informed consent.

With respect to the cost of sequential testing, the issue of increased costs is moot because, as discussed above, the Commission has decided not to adopt this approach.

Cost-benefit comments. Several commenters claimed that the Commission was required by the PPPA to assess the economic impact of the revisions and had not done so. One commenter argued that the statutory

[16] Drug and Pharmaceutical Packaging Materials, May 1991.

[17] Certain household products that meet the size exemption may require special packaging by the Environmental Protection Agency (EPA). EPA, Prevention, Pesticides and Toxic Substances [7506C], EPA–735–F–94–003, For Your Information.

[18] In the Initial Regulatory Flexibility Analysis, 1986 Bureau of Census closure shipment data for companies using Standard Industrial Classification (SIC) 3089 (Plastic Products, Not Elsewhere Classified were cited. The latest available shipment data appear in Bureau of Census, Closures for Containers, MQ34H(92)–5, Summary for 1991, issued July 1992, after which Census discontinued publishing the report due to withdrawal of trade association funding.

terms ''practicable,'' appropriate,'' and ''reasonable'' require the agency to justify the standards on cost-benefit grounds.

The terms ''practicable'' and ''appropriate'' are found in the findings that the Commission is required to make under section 3(a)(2) of the PPPA. 15 U.S.C. 1472(a)(2). Whatever these terms may mean in other contexts, they are specifically described in the legislative history of the PPPA:

> In order to find that special packaging is ''practicable'', the [Commission] must determine, for example, whether special packaging meeting the standard would be susceptible to modern mass-production and assembly-line techniques. Finally, in order to find that special packaging is ''appropriate for such substance'', the [Commission] must examine the substance under consideration and find that packaging complying with the standard is not detrimental to the integrity of the substance and does not interfere with its storage or use.

S. Rep. No. 91–845 at 10. Thus, these terms do not require cost-benefit findings.

Section 3(b) of the PPPA requires the Commission to consider the ''reasonableness'' of any PPPA standard it issues. However, the legislative history of the PPPA states, with respect to section 3(b), the Commission

> Is not required to make a formal finding regarding these issues. This paragraph is intended to prevent the [Commission] from ruling out available evidence on these issues and to insure consideration of that evidence.

S. Rep. No. 91–845 at 10 (emphasis added).

Thus, the Commission is not statutorily required to ''justify'' PPPA standards on cost-benefit grounds, as contended by this commenter. Nevertheless, the Commission is always concerned about the potential costs of its actions. The Commission seeks to fulfill its Congressionally-mandated mission in the most cost-effective manner. Accordingly, the Commission had its staff present the available information on costs and benefits for consideration. [236] That information, which is discussed in detail below, included the likely costs to industry to comply with an older-adult test protocol. Significantly, those costs are overwhelmingly one-time, up-front expenses.

By comparison, the $500 million annual societal costs of accidental childhood ingestions provide a tremendous potential for ongoing benefits from the rule. While the costs of the rule will largely be incurred before the rule's effective date, the substantial benefits of the rule will continue for the foreseeable future.

Moreover, the Commission has taken several actions to potentially reduce the cost of the final rule. These include using an adult panel of ages 50–70, instead of 60–75, and eliminating the sequential test which, in some cases, could require testing up to 400 adults.

Accordingly, the Commission concludes that the costs of the rule are justified in view of the benefits that it will achieve.

For additional discussion of the findings that the Commission is required to make in order to issue this rule, and of the other matters the Commission is required to consider but not make formal findings on, see section V of this notice.

Another commenter indicated that the Commission has not complied with Executive Order 12866, which requires that certain agencies provide the Office of Management and Budget with analyses of the costs and benefits of proposed significant regulatory actions and their alternatives.

Executive Order 12866 imposes a number of requirements on ''agencies,'' as that term is defined in the order. However, under the Order, the term ''agency'' generally does not include independent regulatory agencies, such as the Commission, as that term is defined in 44 U.S.C. 3502(10). Thus, except for preparing a Regulatory Plan and Regulatory Agenda (which the Commission does), the requirements of Executive Order 12866 do not apply to the Commission. Accordingly, the comments relating to the Commission's responsibilities under this Order are inapplicable.

V. Statutory Requirements for Issuing PPPA Standards

A. General

Section 3(a)(1) of the PPPA, 15 U.S.C. 1472(a)(1), authorizes the Commission to issue standards for the special packaging of any household substance if it finds that ''the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance.'' As noted previously, special packaging is packaging that is significantly difficult for children under 5 years of age to open and not difficult for normal adults to use properly. 15 U.S.C. 1471(4).

Section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), requires the Commission to find that the amended standard ''is technically feasible, practicable, and appropriate for [the substances to which it will apply].'' ''Technically feasible'' means that package designs that would meet the requirements of 16 C.F.R. 1700.15(b), and that would be suitable for use with the products subject to the rule, are or can be available. S. Rep. No. 91–845 at 10. A standard is ''practicable'' when special packaging for the products covered by the rule is adaptable to modern mass production and assembly line techniques. *Id.* A standard is ''appropriate'' where special packaging can be made available in forms that are not detrimental to the integrity of the substance and do not interfere with its storage or use. *Id.*

The Commission's staff developed data to support these statutory findings with respect to the 60–75 age group, rather than the participants of ages 50–70 in the panel specified in the final rule. However, these data also support the findings for the 50–70 age group, because packaging that achieves passing results with a 60–75 panel will also meet the 50–70 panel requirement.

Under section 3(b) of the PPPA, 15 U.S.C. 1472(b), the Commission, in issuing a PPPA standard, also is required to consider (a) the reasonableness of the standard, (b) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances, (c) the manufacturing practices of industries affected by the PPPA, and (d) the nature and use of the household substance. In issuing this rule, the Commission has considered these factors.

B. Availability to Children

As noted above, in order to issue a CRP standard, the Commission must find that ''the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance.'' 15 U.S.C. 1472(a)(1). The Commission previously made this finding for the substances listed in 16 C.F.R. 1700.14 when it required that they meet the standards and testing procedure currently specified in 16 C.F.R. 1700.15 and 1700.20. Insofar as those findings relate to the toxicity of the substances and to the general accessibility of the packages to children in the household, these findings are still applicable.

Even though these substances are now marketed in CRP, changes to the adult protocol are needed to adequately protect children from the serious personal injury or serious illness presented by these substances. As explained above, the noncomplying

provision of the PPPA, 15 U.S.C. 1473(a), specifically allows packagers to supply nonprescription regulated products in one size of conventional packaging. 16 C.F.R. 1700.5. In addition, 15 U.S.C. 1473(b) allows regulated prescription products to be provided in non-CRP when requested by the purchaser or directed by the prescriber. Many people exercise these options to obtain packaging that is not CR, and this exposes a significant number of young children to toxic products.

A 1989 CPSC study [112] analyzed a statistical sample of ingestions of medications by children under age 5 that were treated by hospital emergency rooms reporting to the National Electronic Injury Surveillance System (NEISS). This study showed that 44% of the prescription medicines in the study were not dispensed in a CR package. This study also showed that about 40% of the medications (prescription or nonprescription) in the study were not originally packaged in a CR container at the time of purchase and that about 17% of the medications were originally packaged in a CRP but were not in a secured (returned to the CR mode) CRP at the time of the ingestion. The 17% that were no longer in secured CRP consisted of (i) cases where the medication had been removed from the container before the ingestion (about 9%), (ii) cases where the medication was in a CR package but the top was left open (about 6%), and (iii) cases where the medication was in a container with a different top (about 2%).

Further, a 1986 study conducted by the CPSC in conjunction with the AAPCC demonstrated the occurrence of pediatric drug ingestions involving disabled CRP or non-CR packaging. [29] The study involved 9 poison control centers and about 2,000 pediatric drug ingestions. The study showed that, for all medicines in prescription containers other than a unit-dose package, 18% (n=234) had a cap that was loose or off prior to the ingestion. Of those cases involving toxic drugs, approximately (i) 6% involved a CRP with the closure left off or loose, (ii) 17% involved contents transferred from one container to another, and (iii) 18% involved a non-CR package. Thus, improper use of CRP apparently is involved in a substantial number of ingestions by children.

The available information also shows that much of this misuse is caused by regarding the CRP as too difficult to open. This was demonstrated by a 1980 CPSC report of the results of a telephone survey of about 3,000 consumers concerning how they used both drugs and chemical specialty items. [15] In that survey, the primary reason for improper use of CRP for about 42% of the persons who said they left the CR cap off was that it was too difficult to open or close. This was also the primary reason given by 43% of those who said they transferred contents from one container to another and by 59% of those who said they replaced the CR cap with a non-CR cap. These data demonstrate that a major reason why consumers use CR packaging improperly is that the CR packaging is too difficult to open or close.

The problem of operating CRP has a special impact on older consumers, who as a group have more difficulty opening these packages. A survey of 120 non-institutionalized older persons showed that 60% acknowledged having difficulty opening or closing CR medication containers. [9] Sixty-four percent of the women (average age, 70 years) and 36% of the men (average age, 67 years) admitted to having difficulty.

The difficulties experienced by older persons in using CRP, and the resultant tendency to avoid using such packaging, expose children to risk. Data acquired since the 18–45 age panel was selected have shown that there is substantial exposure of young children to adults older than age 60. In the 1989 CPSC NEISS study [112], 16% of the prescription medicines ingested belonged to a grandparent. The percentage of the prescription drugs ingested that belonged to persons age 60 or above was also 16%. These data demonstrate the importance of assuring that older adults can operate CRP by substituting a panel of older persons.

Commission tests [121] show that the inclusion of an older-adult test as part of the PPPA human performance test protocol also will improve the ability of all adults to use CRP. If CRP were easier to use, there would be less motivation to seek out non-CR packaging. Thus, fewer conventional packages would be available to young children who live with or are otherwise exposed to the purchasers. In addition, if complying packages were easier to open and resecure, the packages would more likely be properly resecured after use. Accordingly, substituting a panel of older adults will help protect children by increasing consumer willingness to use CRP and to keep the package properly resecured. This conclusion is supported by the available information.

The Commission has received at least 76 form letters stating that the sender has trouble with CRP, supporting the 60–75 age panel requirement, and pledging that the writer would use CRP if it were inexpensive and easy to use. [140] The Commission also is aware of one study showing that easy-to-use CRP would result in increased proper resecuring of caps. [21]

Previously-available packaging was considered to be difficult to open by 22 to 64% of people from ages 18 to 45, depending on package type. [27, 28] Among people 61 to 75 years old, 27 to 69% found the packages difficult to open. Recent test results with older adults with more senior-friendly packaging differ markedly from the tests cited above. These latter results showed 95 to 99% of the adults (ages 60 to 75) were able to use the reclosable packages tested, and 84 to 91% of the adults rated the packages as ''easy to use.'' [195] Similar results were obtained for non-reclosable packaging.

Thus, the data support the conclusions that a panel of older persons will make CRP easier for normal adults to use; that this will result in more persons buying CRP and using it properly, and that this will ultimately result in fewer accidental poisonings of young children.

For the above reasons, the Commission finds that the degree and nature of the hazard to children in the availability of the substances specified in 16 C.F.R. 1700.14, by reason of packaging that does not comply with the revised protocol, is such that issuance of the revised protocol is required to protect children from serious personal injury or serious illness from handling, using, or ingesting such substances.

C. Technical Feasibility

Introduction

As noted above, technically feasible means that packaging meeting the new standard can be produced. Based on testing done under Commission contract and other information in the record from industry sources, the Commission concludes that special packaging meeting the revised test protocols is technically feasible for all products now required to be in CRP that will be covered by the revised protocols.

The discussion below shows how the Commission reached this conclusion for various categories of packaging as established by ASTM. It is important to note, however, that manufacturers need not continue to use the same type of package that they have in the past. In some cases, it may be easier or less costly to switch to another type of package that is senior-friendly than to obtain or develop a senior-friendly package of the same type that was used previously.

Continuous-Threaded Packaging

Most of the regulated products use or can use this type of CRP. Commercially

available CR ASTM Type IA CT 28mm caps with liner and tamper resistant shrink neck band, on white round plastic 50-tablet bottles [195] were tested under a CPSC contract. This package requires a push down and turn force to open. The CRP has a SAUE of 0.953 (n=100) and a CR effectiveness (CRE) of 100% (n=50), and 90% of the senior adults indicated the package was easy to use. *Id*. The package manufacturer has supplied CPSC with older-adult protocol test data that show other sizes of this type of special packaging also meet the proposed SAUE and CRE requirements. [240]

In addition, a commercially available CR ASTM Type IB CT 35mm cap without liner on a 50-ounce plastic-handled bottle with two locking notches [195] was tested under CPSC contract. The package requires a squeeze and turn force to open. This CRP had a SAUE of 0.983 (n=100) and a CRE of 100% (n=100), and 84% of the senior adults indicated the package was easy to use. *Id*. CPSC has senior protocol test data from the manufacturer showing other sizes of this design CRP also meet the proposed SAUE and CR effectiveness requirements. [240]

For those products requiring metal containers and closures for product stability purposes, one manufacturer has an InterLok plastic over metal 1¼ inch standard alpha nozzle CR cap, requiring a tool to open, that is suitable for use with metal containers. [213] The manufacturer indicated the package likely complies with proposed SAUE and CRE requirements.

Lug-Type Packaging

This type of CRP is typically used for dispensing prescription drugs. A commercially available CR ASTM Type IIA lug, 13 dram, 35mm cap with insert liner on a round amber prescription polypropylene vial without product was tested by CPSC under contract. [160, 195] The package requires a push down and turn force to open. The package had a SAUE of 0.961 (n=100) and a CRE of 100% (n=100), and 89% of the senior adults indicated the package was easy to use. [195] The package manufacturer has supplied CPSC with older adult protocol test data that show other sizes of this type of special packaging would also meet the proposed SAUE and CRE requirements. [240]

The ASTM's Institute for Standards Research (''ISR'') conducted senior adult testing (n=1600) using four protocol testing firms. [211] The CRP tested was the same type from the same company as that tested by CPSC, but with a different production date. Test data from all four testing firms showed the CRP complying with the proposed SAUE requirements. Three of the four testing firms reported compliance with the proposed standards after testing the first set of 100 senior adults.

Snap-Type Packaging

This type of CRP is typically used for prescription drugs and over-the-counter (OTC) nonliquid products, *i.e.*, tablets, capsules, powders, etc. A commercially available CR ASTM Type IIIA snap 33 mm cap with liner and tamper resistant shrink neck band, and foil inner seal on a white round plastic bottle [9] was tested under CPSC contract. [160, 195] This package requires arrows to be lined up and an upward force applied to open. This CRP had a SAUE of 0.992 (n=100), a CRE of 97% (n=100), and 91% of the senior adults indicated the package was easy to use. [195] There is no reason to believe that other sizes of this design CRP cannot be made senior-friendly.

Pouches and Blister Packaging

The non-reclosable single-use CR pouch and blister packaging are used for a variety of products and can be used for most regulated products. Four commercially available packages containing product, two CR pouches and two CR blisters, were tested by CPSC under contract as received from the manufacturer. The packages tested are as follows:

A CR ASTM type IVA foil pouch with internal (hidden) tear notch opening was tested with 400 seniors and had a SAUE of 0.981 after the first 100 adults tested, and 80.5% of the senior adults indicated the package was easy to use. [194] This package design is presently used for many products.

The same type of foil pouch was also tested with instructions to use scissors to open. [194] In this case, it is classified as a CR ASTM type IVC foil pouch. The CR pouch, opened with a tool, had a SAUE of 1.000 after the first 100 adults tested, and 99% of participants indicated the package was easy to use. *Id*. Test results show that senior adults can successfully open CR pouches with a tool (scissors) and find it easy to do.

A CR ASTM type VIIID, semi-rigid blister with peel and push out opening, blister card ($3 \times 4 = 12$ blisters) was tested with 400 seniors and had a SAUE of 0.961 after the first 100 adults tested, and 81% of participants indicated the package was easy to use. [194] This package design is used for a number of products at this time.

The ASTM/ISR conducted senior adult testing (n=1600) on the same type of semi-rigid blister from the same manufacturer and containing the same product as the Commission had tested using four protocol testing firms. [211] Test data from all four testing firms showed the CRP complying with the proposed SAUE requirements. Three of the four testing firms reported compliance with proposed standards after the first test of 100 senior adults.

A CR ASTM type VIIIE, semi-rigid blister with internal tear notch and instructions to use scissors to open, blister card ($2 \times 3 = 6$ blisters) was tested with 400 seniors and had a SAUE of 0.942 after two sets of 100 adults were tested. [194] Eighty-four percent of the participants indicated the package was easy to use. *Id*. This design package is used for a number of products at this time that are regulated, *i.e.*, hazardous, at the one- or two-unit level. Test results show that senior adults can successfully open CR blisters with a tool (scissors) and find it easy to do.

Tests with commercially available products show there is senior-friendly CR pouch and blister packaging on the market. [194] Such packaging is, therefore, technically feasible. Some products using CR pouch and blister packaging presently include the option of using a tool (scissors) to open the package. Data show that the use of a tool (scissors) increases the number of seniors able to open the package and the ease with which they open the package. Id.

Aerosols and Pumps

Currently, a few PPPA-regulated substances, such as oven cleaners, use this type of packaging. Products that must be in aerosol form are not subject to the new senior-friendly requirements. They will be, however, subject to the revised child test requirements and will remain subject to the current adult-test requirements.

One CRP manufacturer has advertised its CR overcap—ASTM type VIID, a permanently attached hinged overcap that requires a tool (coin) to open—to be senior-friendly. [232, Ref. 15] This design can be used for aerosols and certain mechanical pump dispensers. Based upon past experience with such designs, the Commission believes that this overcap could be developed so it would be both child-resistant and senior-friendly. If a tool is required to open the package, it will likely comply with the CR effectiveness standards. With the leverage afforded when using a tool (e.g., a coin) and with the proper opening force a senior-friendly package can be accomplished.

Developing CR, SAUE packaging for the small capacity mechanical pump package may require more time than other package types. A CR overcap with

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, VIIID, 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,

there is no reason why these guidelines should not become effective as quickly as possible.

VII. Environmental Protection Agency

The Environmental Protection Agency (''EPA'') enforces the Federal Insecticide, Fungicide and Rodenticide Act (''FIFRA''), as amended (7 U.S.C. 136–136y). Under that Act, EPA has the authority to protect people and the environment from the adverse effects of pesticides by ensuring that pesticide products are applied, stored, and disposed of in a manner consistent with the product registration.

The Administrator of EPA is authorized to establish standards with respect to the package, container, or wrapper in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by FIFRA. FIFRA specifies that the standards established by EPA must be consistent with those established under the authority of the PPPA. Thus, packages that comply with the PPPA regulations would also comply with the standards established by EPA for products regulated under FIFRA. However, EPA would retain the authority to exempt products, either completely or under stated conditions, from the requirement that products regulated under FIFRA have CRP.

Since the Commission is amending its regulations under the PPPA, EPA can be expected to make any necessary amendments to its regulations for packaging so that EPA's regulations will be consistent with those established by the Commission. However, the Commission is not in a position to fully assess how the changes may affect all the products subject to regulation by EPA under FIFRA. For example, some of the containers subject to FIFRA are much larger, and have much larger and more massive closures, than do the household products regulated by CPSC under the PPPA. Such products, that comply with the present PPPA requirements, may not be able to comply with the senior-adult test panel or reduced testing times being proposed for products subject to the PPPA. However, if necessary, EPA has the option of allowing certain containers to comply with a standard incorporating a 5-minute test of the 18–45 age group.

VIII. Regulatory Flexibility Analysis [236]

A. General

The Regulatory Flexibility Act (Pub. L. No. 96–345) requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities, when a notice of proposed rulemaking is published in the **Federal Register**. In its proposal to revise the protocol for testing CRP under the PPPA, the Commission made an initial determination that the effect of the revisions depended upon the amount of package testing needed and the potential cost of research and development and equipment modification, if necessary, to enable closures/packages to meet the revised test protocol. The potential cost of meeting marketing requirements of other government agencies was also unknown.

CPSC received comments on the proposal that provided information on anticipated impacts on companies. Some comments were specific to an individual company; some comments were more generalized and came from trade associations representing small and large businesses. The types of businesses impacted by the proposed revisions include: closure/package manufacturers; household product manufacturers/packagers, pharmaceutical packagers, and pharmacies.

Estimates of the number of businesses in the various market segments are based on data from government sources, trade associations, and trade publications. These sources did not provide specific information on the size of the firms. Small entities that are unaffiliated with trade organizations and that did not comment on the proposal are included in the estimates only to the extent that they reported (anonymously) to government sources.

B. Closure Manufacturers

The Bureau of the Census reported 1991 CR shipment data from 40 or fewer manufacturers (none by name). However, CPSC staff identified about 70 manufacturers of CR closures, many of which were likely included in the Census data. According to industry spokespersons, the CR closure segment of the market is highly concentrated, with the 4 largest manufacturers of plastic closures accounting for an estimated 80% of the CR closure market. [236] Few, if any, of the more than 60 other manufacturers (an unknown number of which may be small) produce CRP as a primary product line, since the CR market is itself only a small fraction of the closure market.

At a minimum, closure manufacturers will incur the costs of testing existing packages for SAUE. Failing packaging cannot be filled after the expiration of the 18-month exemption from compliance (unless an additional temporary stay of enforcement is granted), but such packaging may be modified or redesigned if economically feasible. The costs of changes are expected to fall on the customer and, in most cases, to pass through to the consumer. It is unlikely that a substantial number of small firms will experience severe or permanent adverse impacts as a consequence of the final rule.

CPSC received only one comment from a self-identified small business that expected ''onerous and undue hardship.'' CR closures account for 20% of this company's business. One aspect of the burden concerns timing, which the Commission has addressed by granting an 18-month exemption from compliance after the effective date. In addition, the company can apply for an additional temporary stay of enforcement if good-faith efforts do not enable compliance by the expiration of the 18-month exemption.

C. Household Product Manufacturers and Packagers

Two trade associations, representing over 900 firms, commented on the proposal. One association said about 65% of its members (almost 300) were small businesses; the other association (representing about 500 members) did not respond to a staff request for this information. Comments from the associations and from several large household product manufacturers centered around the cost of testing, the availability of packaging, and the timing of the implementation of the rule. CPSC did not receive comments from individual self-identified small household product manufacturers or packagers. The manufacturers and packagers of household products that must be packaged in metal containers or aerosol form will benefit from the Commission's decision not to include these products within the scope of the products subject to the senior-friendly requirements of the revised rule.

Small household product manufacturers will incur the costs of testing proprietary packages, if they use such packaging. Economic considerations will guide decisions by small companies on whether to pursue SAUE package development (if proprietary packages fail the revised

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,

(*iv*) No other suitable packaging type would provide adequate shelf-life for the product's intended use, or

(*v*) Any other reason clearly demonstrates that such packaging is required.

(*2*) *Presumption.* In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product, or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure.

(*3*) *Justification.* A manufacturer or packager of a product that is in a metal container or aerosol form that the manufacturer or packager contends is not required to comply with the SAUE requirements of § 1700.20(a)(3) shall provide, if requested by the Commission's staff, a written explanation of why the product must have a metal container or be an aerosol. Manufacturers and packagers who wish to do so voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

3. Section 1700.20(a) is revised to read as follows:

§ 1700.20 Testing procedure for special packaging.

(a) *Test protocols.* (1) *General requirements.*

(i) *Requirements for packaging.* As specified in § 1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this § 1700.20.

(ii) *Condition of packages to be tested.* (A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies:

(*1*) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(*2*) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(*3*) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) *Reclosable packages—adult tests.* In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to ''take a set.'' If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) *Child test.* (i) *Test subjects.* (A) *Selection criteria.* Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in Table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42–44 months, 40% of the children in each group shall be of age 45–48 months, and 30% of the children in each group shall be of age 49–51 months. The children's ages in months shall be calculated as follows:

(*1*) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

(*2*) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days. (e.g.,

$$\begin{array}{r} 8 \;/\; 03 \;/\; 1990 \\ -6 \;/\; 23 \;/\; 1986 \\ \hline 2 \quad -20 \quad\quad 4 \end{array}$$

(*3*) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date (i.e., 4×12= 48; 48+2= 50). This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

(*4*) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is −16 or less, subtract 1 month. If the number of days is between −15 and +15 inclusive, no change is made in the number of months. Thus, for the example given above, the number of days is −20, and the number of months is therefore 50−1=49 months.

(B) *Gender distribution.* The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. A parent or guardian of each child shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) *Test failures.* A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) *Sequential test.* The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in Table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30% of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be

used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in Table 1 are cumulative.

TABLE 1—NUMBER OF OPENINGS: ACCEPTANCE (PASS), CONTINUE TESTING, AND REJECTION (FAIL) CRITERIA FOR THE FIRST 5 MINUTES AND THE FULL 10 MINUTES OF THE CHILDREN'S PROTOCOL TEST

Test panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0–3	4–10	11+	0–5	6–14	15+
2	100	4–10	11–18	19+	6–15	16–24	25+
3	150	11–18	19–25	26+	16–25	26–34	35+
4	200	19–30	.....	31+	26–40	.....	41+

(iv) *Test procedures.* The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children, for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

Standardized Child Test Instructions

1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials (e.g., the closure liner) to ''take a set.'' Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the same sequence as the first opening and resecuring. The packages shall not be opened and resecured again prior to testing. The name of each tester and the package numbers that he/she opens and resecures shall be recorded and reported. It is not necessary for the testers to protocol test the packages that they opened and resecured.

4. The children shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.

10. The tester shall use a stopwatch(s) or other timing devices to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, ''PLEASE TRY TO OPEN THIS FOR ME.''

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversation with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., ''please try to open the package'').

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

17. A child shall not be allowed to try to open the other child's package.

18. If a child opens his/her package, the tester shall say, ''THANK YOU,'' take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate ''demo'' package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, ''WATCH ME OPEN MY PACKAGE.''

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, ''NOW YOU TRY TO OPEN YOUR PACKAGES.''

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, ''YOU CAN USE YOUR TEETH IF YOU WANT TO.'' This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, ''THANK YOU FOR HELPING.'' If children were told that they could use their teeth, the tester shall say, ''I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT

THINGS LIKE THIS IN YOUR MOUTH AGAIN'' In addition, the tester shall say, ''NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK.''

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

(3) *Senior-adult panel.* (i) *Test subjects.* Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50–54 years of age, 25% of participants shall be 55–59 years of age, and 50% of the participants shall be 60–70 years old. Seventy percent of the participants of ages 50–59 and ages 60–70 shall be female (17 or 18 females shall be apportioned to the 50–54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) *Screening procedures.* Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or ''special'') closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm ± 18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce ± ½ ounce for the CT-type closure and 8 drams ± 4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) *SAUE.* The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) *Test procedures.* The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

Test Instructions for Senior Test

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Examples of the forms used by the Commission staff for testing are shown at § 1700.20(d). Before beginning the test, the tester shall say, ''PLEASE READ AND SIGN THIS CONSENT FORM.'' If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the package are the only exceptions.

6. To begin the first 5-minute test period, the tester says, ''I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP.'' (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, ''PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP.'' (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, ''PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.'' After the participant opens the package, the tester says, ''PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.'' (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resecuring times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, ''ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?'' If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, ''THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP.'' (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, ''PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER.'' After the participant opens the package, the tester says, ''PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP.'' (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and finished closing the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, ''ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?'' If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, ''PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.'' The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, ''PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE.'' The time to open and resecure, or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-seniors panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

(4) *Younger-adult panel.* (i) One hundred adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70% of whom are female, shall comprise the test panel for younger adults. Not more than 35% of adults shall be obtained or tested at any one site. No individual tester shall administer the test to more than 35% of the adults tested. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to open and properly resecure the special packaging as will appear on the package as it is delivered to the consumer. Five minutes shall be allowed to complete the opening and, if appropriate, the resecuring process.

(ii) Records shall be kept of the number of adults unable to open and of the number of the other adults tested who fail to properly resecure the special packaging. The number of adults who successfully open the special packaging and then properly resecure the special packaging (if resecuring is appropriate) is the percent of adult-use effectiveness of the special packaging. In the case of unit packaging, the percent of adult-use effectiveness shall be the number of adults who successfully open a single (unit) package.

4. Add a new § 1700.20(d), reading as follows.

§ 1700.20 Testing procedure for special packaging.

* * * * *

(d) Recommendations. The following instructions and procedures, while not required, are used by the Commission's staff and are recommended for use where appropriate.

(1) *Report format for child test.*

A. Identification

1. Close-up color photographs(s) clearly identifying the package and showing the opening instructions on the closure.
2. Product name and the number of tablets or capsules in the package.
3. Product manufacturer.
4. Closure model (trade name—e.g., ''KLIK & SNAP'').
5. Closure size (e.g., 28 mm).
6. Closure manufacturer.
7. Closure material and color(s) (e.g., white polypropylene).
8. Closure liner material.
9. TAC seal material.
10. Opening instructions (quote exactly, e.g., ''WHILE PUSHING, DOWN, TURN RIGHT''). Commas are used to separate words that are on different lines.
11. Symbols, numbers, and letters found inside the closure.
12. Package model.
13. Package material and color.
14. Net contents.
15. Symbols, numbers, and letters on the bottom of the package.
16. Other product identification, e.g., EPA Registration Number.

B. Procedures

1. Describe all procedures for preparing the test packages.
2. Describe the testing procedures.
3. Describe all instructions given to the children.
4. Define an individual package failure.

C. Results

1. Openings in each 5-minute period and total openings for males and for females in each age group.
2. Opening methods (e.g., normal opening, teeth, etc.).
3. Mean opening times and standard deviation for each 5-minute test period.
4. The percentage of packages tested at each site as a percentage of total packages.
5. The percentage of packages tested by each tester as a percentage of total packages.
6. Child-resistant effectiveness for the first 5-minute period and for the total test period.

(2) *Standardized adult-resecuring test instructions.* CPSC will use the adult-resecuring test where an objective determination (e.g., visual or mechanical) that a package is properly resecured cannot be made. The adult-resecuring test is performed as follows:

Adult-Resecuring Procedure

1. After the adult participant in either the senior-adult test of 16 CFR 1700.20(a)(3) or the younger-adult test of 16 CFR 1700.20(a)(4) has resecured the package, or at the end of the test period (whichever comes first), the tester shall take the package and place it out of reach. The adult participant shall not be allowed to handle the package again.
2. The packages that have been opened and appear to be resecured by adults shall be tested by children according to the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.
3. Using the results of the adult tests and the tests of apparently-resecured packaging by children, the adult use effectiveness is calculated as follows:

a. *Adult use effectiveness.*

1. The number of adult opening and resecuring failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resecured packages, equals the total number of failures.
2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness.

(3) Report format for adult-resecuring test.

A. Identification

1. Close-up color photograph(s) clearly identifying the package and showing the top of the closure.
2. Product name and the number of tablets or capsules in the package.
3. Product manufacturer.
4. Closure model (trade name).
5. Closure size (e.g., 28 mm).
6. Closure manufacturer.
7. Closure material and color(s) (e.g., white polypropylene)
8. Closure liner material.
9. Symbols, numbers, and letters found inside the closure.
10. TAC seal material.
11. Opening instructions (Quote exactly, e.g., ''WHILE PUSHING, DOWN, TURN RIGHT''). Commas are used to separate words that are on different lines.
12. Package model.
13. Package material and color.
14. Net contents.
15. Symbols, numbers, and letters on the bottom of the package.
16. Other product identification, e.g., EPA Registration Number.

B. Procedures

1. Describe all procedures for preparing the test packages.
2. Describe the testing procedures in detail.
3. Describe all instructions given to participants.
4. Define an individual package failure and the procedures for determining a failure.

C. Results

Adult Test

1. Total packages opened and total packages resecured; packages opened by males and by females; and packages resecured by males and by females.
2. Mean opening times and standard deviation for total openings, total openings by females, and total openings by males.
3. Mean resecuring times and standard deviation for total resecurings, total resecurings by females and total resecurings by males.
4. The percentage of packages tested at each site as a percentage of total packages.
5. The percentage of packages tested by each tester as a percentage of total packages.
6. Methods of opening (e.g., normal opening, pried closure off, etc.)

Child Test

1. Openings in each 5-minute period, and total openings, for males and females in each age group.
2. Opening methods.
3. Mean opening times and standard deviation for each 5-minute test period.
4. The percentage of packages tested at each site as a percentage of total packages.
5. The percentage of packages tested by each tester as a percentage of total packages.

(4) Consent forms. The Commission uses the following consent forms for senior-adult testing reclosable and unit-dose packaging, respectively.

1. *Reclosable packages.*

[Testing Organization's Letterhead]

Child-Resistant Package Testing

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened and properly closed by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

1. I will give you a package and ask you to read the instructions and open and properly close the package.
2. I will then give you an identical package, and ask you to open and properly close it.
3. I may ask you to open some other types of packages.
4. The packages may be empty or they may contain a product.
5. I will ask you whether you think the child-resistant package was easy or hard to use.

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate _____
Signature _____
Date _____
Zip Code _____

Office Use

Site: _____
Sample Number: _____
Test Number: _____
Package Number: _____

2. Unit-dose packages.

[Testing Organization's Letterhead]

Unit Dose Child-Resistant Package Testing

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

1. I will give you a package and ask you to read the instructions, open one unit, and remove the contents.
2. I will then give you an identical package, and ask you to open one unit and remove the contents.
3. I may ask you to open some other types of packages.
4. I will ask you whether you think the child-resistant package was easy or hard to use.

Consent Form for Child-Resistant Package Testing

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.

Birthdate _____
Signature _____
Date _____
Zip Code _____

Office Use

Site: _____
Sample Number: _____
Test Number: _____
Package Number: _____

§ 1700.14 [Amended]

5. Section 1700.14(a) introductory text is amended by inserting ''meeting the requirements of § 1700.20(a)'' after ''is such that special packaging''.

Dated: July 11, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Appendix I—List of Relevant Documents

(This Appendix will not be printed in the Code of Federal Regulations.)

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[FR Doc. 95–17436 Filed 7–20–95; 8:45 am]

BILLING CODE 6355–01–P