

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 resealing it to a CR condition. The adult-resealing test proposed by CPSC can be used to determine whether packages have been properly resealed 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 resealed 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.