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