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