16 CFR Part 1701

Prescription Drugs Distributed To Prescribing Practitioners; Withdrawal of Proposed Statement of Policy and Interpretation

AGENCY: Consumer Product Safety Commission.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Consumer Product Safety Commission withdraws a proposed rule that would have required all prescription drugs that are subject to a child-resistant packaging standard and that are distributed to physicians and other prescribing practitioners to be in child-resistant packaging if the immediate packages in which the drugs are distributed by the manufacturer are intended to be the packages in which the drugs are dispensed to the consumer. The proposal is being withdrawn because the Commission lacks data concerning the costs and benefits of such a rule and the available data are not sufficient to establish the portion of reported ingestions that may involve drugs being distributed by practitioners in packaging that is not child-resistant.

DATE: The withdrawal of the proposal is effective March 5, 1984.

FOR FURTHER INFORMATION CONTACT: Charles M. Jacobson, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, D.C. 20207, phone (301) 492–6400.

SUPPLEMENTARY INFORMATION: Section 3 of the Poison Prevention Packaging Act of 1970 ("the act"), 15 U.S.C. 1472, authorizes the establishment of standards requiring "special packaging" for certain household substances in order to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. "Special packaging" is packaging that is designed or constructed to be (1) significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for normal adults to use properly (15 U.S.C. 1471(4)). A household substance is one which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household.

In the **Federal Register** April 16, 1973 (38 FR 9431, 9432), a regulation (now 16 CFR 1700.14(a)(1)) was issued that requires that all oral prescription human drugs be supplied in special packaging.

The Commission's policies concerning the manufacturer's distribution of prescription drugs in noncomplying packaging intended for consumer use have been different, depending on whether the manufacturer distributed the drug to a pharmacy or to a prescribing practitioner. The Commission has codified a statement (16 CFR 1701.1) of its long-standing policy that when prescription drugs are distributed by manufacturers to pharmacies in packages that are intended to be dispensed directly to consumers, all immediate containers of such drugs must meet the standards for special packaging. Whether a manufacturer intends that a package will be the one in which the drugs are dispensed to the consumer can be determined from the type of package, whether the ancillary instructions provided on the package (such as for storage or handling) are intended for consumers, and other factors.

However, the previous policy of the Commission, and of the Food and Drug Administration which preceded the Commission in administering the Poison Prevention Packaging Act of 1970, was that such drugs could be distributed to prescribing practitioners in either complying or noncomplying packaging. The reason that this policy was followed in the past was that since, under section 4(b) of the act, the prescribing practitioner has the discretion to prescribe drugs for consumers in noncomplying packaging, there was no apparent need to require that the drug be distributed to the practitioner in complying packaging. The policy of not requiring drugs subject to child-resistant packaging standards to be in child-resistant packaging when consumer packages of such drugs are distributed to physicians or other prescribing practitioners has been the subject of much debate over the years. A strong argument can be made that the opposite interpretation is more consistent with the terms of the PPPA. The legislative history of the act shows that it was the intent of the act for special packaging to be the rule and not the exception. Futhermore, it seems that the practitioners would be more likely to dispense these drugs in child-resistant packaging if that were the form of packaging supplied to the practitioner. For these reasons, the Commission previously proposed to change its policy so that manufacturers of thses drugs would be required to package them in child-resistant packaging if the drugs were furnished to the practitioner in packages intended to be dispensed to the consumer. 43 FR 12029; March 23, 1978.

The Commission received 15 comments in response to the proposal to change its policy applicable to manufacturers supplying drugs in consumer packages to practitioners. Comments from a university medical center, two pharmaceutical associations, and a pharmacists' association supported the proposed change in policy. The remaining comments, from the Pharmaceutical Manufacturers Association and various pharmaceutical manufacturers, either opposed the issuance of the proposed policy change or suggested modifications to the rule.

In the comments which were received in response to the proposed statement of policy, 2 comments raised the question of whether unit package samples of eight units or less which do not contain an amount of drug which would be harmful to a 25-pound child would automatically comply with the special packaging requirement. The response to these comments is that such packaging would comply.

The vast majority of physicians' samples are packaged in unit packaging.

Unit packaging is packaging in which each dosage unit, e.g., a tablet or a capsule, is individually packaged in such a way as to protect the integrity of the product. A unit package may or may not be attached to other individual unit packages or packaged in an outer carton. The most common types of unit packaging used for physicians' samples are blister packaging or strip packaging.

The protocol for determining the child-resistance of special packaging (16 CFR 1700.20) contains special provisions for defining a package failure for unit packaging. For containers other than unit packaging, a failure occurs when any child opens the special packaging or gains access to its contents during the test. In the case of unit packaging, however, a test failure occurs when any child opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness to a 25-pound child, or to more than 8 individual units, whichever number is lower.

The Commission staff estimates that over 75% of physicians' samples are packaged in unit packaging and that most if not all of this unit packaging would contain not more than 8 individual units. The Commission's staff also believes that the majority of products distributed as physicians' samples would be of a low enough toxicity that more than 8 units would be required to cause serious injury or illness to a 25-pound child. Therefore, it seems likely that the majority of physicians' samples already comply.

After considering the comments and other available information, the Commission concluded that issuance of the proposed policy at this time is not appropriate because information currently available does not establish that there is a significant risk to young children as a result of present packaging practices for physicians' samples. Furthermore, the Commission lacks data on the costs and benefits of the proposed policy change. Since the Commission lacks data showing that the proposed policy change is needed, the Commission has decided to withdraw the proposal.[1] If information becomes available in the future showing risks to young children associated with physicians dispensing samples without child-resistant packaging, the Commission at that time could propose an appropriate policy change based on the new information.

The Commission would also like to point out that, regardless of the type of packaging supplied to the practitioner by the sample manufacturer, the PPPA establishes that a dispensing practitioner is responsible for placing drugs they supply to consumers in child-resistant packaging unless the practitioner decides that child-resistant packaging is not appropriate in a particular case. The Commission believes that the purpose of 15 U.S.C. 1473(b), which allows medical practitioners to order that prescribed substances subject to PPPA requirements be dispensed in noncomplying packaging, is to allow practitioners to see that persons, such as the elderly and handicapped, who cannnot use substances in complying packaging, can have these substances in non-complying packaging.

Conclusion

Therefore, for the reasons explained above, the Commission withdraws the proposal of March 23, 1978 (43 FR 12029) to issue a new § 1701.2 in title 16 of the CFR.

List of Subjects in 16 CFR Part 1701

Consumer protection, Hazardous materials, Infants and children, Packaging and containers, Poison prevention, and Prescription drugs.

Dated: February 28, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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[1] The withdrawal notice was approved by Chairman Nancy Harvey Steorts and Commissioners Stuart M. Statler and Terrence M. Scanlon. Commissioner Saundra B. Armstrong, who was not a member of the Commission when this matter was previously considered, abstained from voting on it.