

U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, D.C. 20207

MINUTES OF COMMISSION MEETING January 5, 1995 4330 East West Highway Bethesda, Maryland

The January 5, 1995, meeting of the U. S. Consumer Product Safety Commission was convened in open session at 10:00 a.m. by Chairman Ann Brown. Commissioner Mary Sheila Gall was present.

Agenda Item: PPPA Protocol Revisions

The Commission considered a final rule that would revise the child-resistant (CR) packaging test protocols under the Poison Prevention Packaging Act (PPPA) to make CR packaging easier for adults to open while continuing to provide child-resistant protection for young children. The Commission was briefed by the staff on a recommended final rule at the Commission meeting of December 20, 1994. (Ref: staff briefing package dated December 6, 1994, and draft <u>Federal Register</u> document dated December 19, 1994.)

At today's meeting the staff reviewed and discussed with the Commission several submissions on this rulemaking matter received since the December 20 briefing, from the Closure Manufacturers Association (December 23, 1994, and January 4, 1995), the Nonprescription Drug Manufacturers Association (January 3, 1995), the Chemical Specialties Manufacturers Association (January 3, 1995), and the American Association of Retired Persons (January 4, 1994).

Following discussion, Chairman Brown moved that the Commission approve the draft rule that was recommended by the staff and forwarded to the Commission on December 19, 1994, with the modification that the rule would provide for a one-year enforcement exemption for those products that are now marketed in metal cans or in aerosol dispensers, provided the manufacturer certifies to the Commission's staff that the additional time is reasonably needed to convert to packaging that meets the new protocol. The staff would make the appropriate changes to the rule and submit the changes for the Commission's approval. This motion failed by vote of 1-1, with Chairman Brown voting in favor and Commissioner Gall voting against.

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PPPA Protocol Revisions, continued

Commissioner Gall moved that the Commission accept the recommended senior friendly protocol revisions for all products regulated under PPPA except products that must use metal or aerosol containers. Though these containers would not have to meet senior friendly protocol requirements, they must continue to use child resistant packaging. The staff would be directed to modify the draft <u>Federal Register</u> notice to reflect this change and to include a procedure to determine what products must use metal or aerosol containers. The revised <u>Federal Register</u> notice would then be submitted to the Commission for ballot vote. This motion passed unanimously (2-0).

Chairman Brown and Cornmissioner Gall each filed a statement on the PPPA protocol revision matter, copies attached.

There being no further business on the agenda, Chairman Brown adjourned the meeting.

For the Commission:

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Sadye E. Dunn Secretary

Attachments

Statement of Chairman Ann Brown Changes to Child-Resistant Packaging Test Protocols January 5, 1995

I have today voted to issue a final rule to require changes to the child-resistant packaging test protocols under the Poison Prevention Packaging Act. These changes are intended to make closures more "senior-friendly," while still maintaining their child-resistant features. I voted for the rule because I am convinced it will increase protection against poisoning for children under age 5. If adults leave caps off because they are too difficult to use, we do not achieve the purposes of child-resistant packaging. If the caps are easy to use, they are more likely to be used properly. This new rule will make caps easier to use, adults will use them as intended, and the result will be that children will less frequently have access to drugs or household products that can harm them.

Today's rule is a gift to American families, especially to older persons and those of any age who have been frustrated by the difficulty of opening and using child-resistant caps on medicine or most household products. It is a gift of life and safety, a gift which will allow persons of all ages to help protect innocent children against accidental poisoning. This rule change will save children's lives. It will realize more effectively than ever the goal of the original Poison Prevention Packaging Act.

The staff recommended that this rule change apply to all pharmaceutical and household products that are required to be in child-resistant packaging. Child-resistant packaging is or soon will be available for almost all of these products. However, manufacturers of household products packaged in metal and aerosol cans made the case, convincingly, in my view, that they may require additional time to convert to packaging that meets the new protocol. Although there is a temporary 6-month enforcement exemption provision in the rule, I made a motion to give manufacturers of products in these two categories of packaging a special one-year enforcement exemption, if they needed it, beyond the effective date which applied to all other packaging. I believed that this was a fair and appropriate response to legitimate industry concerns, while still adhering to our goal of increasing protection for children as quickly as reasonably possible. However, given the importance of moving to more senior-friendly packaging, I supported Commissioner Gall's motion to cover all products except those that must use metal or aerosol containers. I encourage these manufacturers to move forward. We will revisit this issue.

I have fully considered industry concerns about the rule, including its potential costs. But, I believe the staff has fully and completely answered the questions which have been raised about the proposed test protocol and about the technical feasibility, practicability, and appropriateness of child-resistant packaging. The new test requirements are fair and reasonable. Adoption of this new rule will likely spur competition to develop new innovative designs that will meet the demand for easy-to-use child-resistant packaging. More effective child-resistant packaging will reduce injuries and deaths from poisonings; in so doing it will save on the cost of medical expenses and reduce health care costs. This accomplishment, of which the Commission can be proud, will enhance the lives of all Americans.

Statement of Commissioner Mary Sheila Gall on Final Rule to Require Changes to Child-Resistant Packaging Test Protocols

January 5, 1995

Today I have voted to adopt a limited version of the senior friendly protocol revision of the Poison Prevention Packaging Act (PPPA) as proposed by the staff. The Commission's decision limits the scope of this rulemaking to closures that are technically feasible, practicable and appropriate, which is to say, closures that will be commercially available by the effective date of this regulation. I am pleased that the Chairman has joined me in support of this action.

The vote reflects a common sense approach to government regulation. Industry has indicated without exception their support for the concept of senior friendly child-resistant packaging. Their representatives have expressed well-founded concerns that where packaging has not, and in some cases may not be developed and marketed, regulatory coverage is not justified. I agree. This is why I moved to limit coverage to closures for which this finding can be made.

Furthermore, the record indicates that a significant factor contributing to ingestion by children is the difficulty consumers have in opening current child-resistant packaging. By requiring the use of senior friendly (easy open) packaging that maintains its child-resistance, more consumers will use this packaging appropriately. This will reduce accidental ingestions by children and as a result reduce their risk of serious personal injury or illness. This is the primary goal of the PPPA. Today's action is consistent with that purpose.