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

MINUTES OF COMMISSION MEETING
June 23, 2000
4330 East West Highway
Bethesda, Maryland

The June 23, 2000, 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 and Commissioner Thomas H. Moore were present.

Agenda Item: Oral Drugs Switched From Prescription to Over-the-Counter (OTC) Status

The Commission considered the staff's recommendation to propose that child-resistant packaging requirements for oral prescription drugs continue when such drugs are granted over-the-counter (OTC) status by the Food and Drug Administration. The Commission was briefed by the staff on this matter at the Commission meeting of June 7, 2000. (Ref: staff briefing package dated May 16, 2000.) The Commission also received supplemental information from the staff responding to questions raised by Commissioner Moore.

On motion of Chairman Brown, the Commission by unanimous vote (3-0) authorized staff to prepare a draft Federal Register notice of proposed rulemaking (NPR) for Commission consideration and vote, requiring special packaging for OTC-switched oral prescription drugs.

Chairman Brown, Commissioner Gall, and Commissioner Moore filed separate statements on the matter, copies attached.

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

For the Commission:

Sadye E. Dunn

Sadye E. Dunn
Secretary

Attachments

THE CHAIRMAN

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

Decision Statement
The Honorable Ann Brown, Chairman
U.S. Consumer Product Safety Commission

OTC Switches

June 23, 2000

I voted today for the Commission to proceed with a rulemaking proposal to require child-resistant packaging for oral prescription drugs that are granted over-the-counter status by the Federal Food and Drug Administration. The staff is directed to draft a proposed rule for Commission consideration.

Under current rules, these drugs are required to be in child-resistant packaging while they are prescription drugs. It only makes sense that CR packaging rules continue to apply to these drugs when they are switched to over-the-counter status.

The Poison Prevention Packaging Act (PPPA) has been the first line of defense in preventing child-related poisonings. This important statute gives the Commission authority to require child-resistant packaging for hazardous substances and drugs. Since 1972, the Commission has required CR packaging for 12 categories of OTC drugs, 5 of which have been drugs which have been switched from prescription to OTC status. These actions have reduced child-related unintentional poisonings, injuries and deaths.

I believe the proposed rule would achieve these same objectives with greater timeliness, fewer resources, enhanced safety for kids and more certainty for industry.

The Commission's decision to move forward with this proposed rule is, indeed, timely. Next week, the Federal Food and Drug Administration FDA will begin public hearings to examine OTC issues, including the status of OTC products, the criteria FDA should use in making decisions on the availability of OTC drugs, and how FDA can be assured that consumers understand the issues relating to OTC drugs.

With over-the-counter drugs becoming as available as chewing gum, ensuring the safety of kids is just plain good government: good for consumers, beneficial for this agency, and attractive for the pharmaceutical and closure industry.

I look forward to receiving widespread public and industry support for this proposed rule. It's just good common-sense government.

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WASHINGTON, DC 20207

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Commissioner

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STATEMENT OF THE HONORABLE MARY SHEILA GALL IN SUPPORT OF ISSUANCE OF NOTICE OF PROPOSED RULEMAKING REQUIRING CR-PACKAGING FOR OTC-SWITCHED DRUGS

June 23, 2000

The laws and regulations under the jurisdiction of the Food and Drug Administration (FDA) governing oral prescription drugs require that they be placed in child-resistant (CR) packaging unless the drug manufacturer obtains an exemption. When FDA switches a drug from prescription to over-the counter (OTC) status, manufacturers may, in the absence of a Commission rulemaking under the Poison Prevention Packaging Act (PPPA), market the drug in non-CR packaging. The interaction of the laws administered by FDA and the Commission clearly result in a "regulatory gap." This regulatory gap resulted in the introduction of ibuprofen in non-CR packaging in significant quantities.

Aside from the example of ibuprofen, however, this regulatory gap has not been a significant problem. Since 1976 twenty-two oral prescription drugs have been switched to OTC status. In six cases (including ibuprofen) the Commission promulgated rules requiring CR packaging. In the remaining sixteen cases, no recommendation has yet to be made by the staff for requiring CR packaging, although the staff presently believes that it would recommend CR packaging for four of the drugs and might recommend it for another seven or eight. The proposed rule would not cover any of these drugs and they will have to be the subjects of separate rulemakings.

Because there is a regulatory gap, and because this gap has resulted in adverse consequences in at least one case, I voted today to approve this Notice of Proposed Rulemaking. I am concerned that the effect of the regulation will be to shift the burden of proof from the Commission to establish the need for CR-packaging to a drug manufacturer to prove the lack of such need. I am, therefore, very interested in hearing from affected parties about how they perceive this rule will affect the packaging practices of the OTC drug industry and the safety of the children whom the PPPA is designed to protect.

STATEMENT OF COMMISSIONER THOMAS H. MOORE
On the Proposed PPPA Rule for Oral Drugs Switched from Prescription to Over-The-Counter Status
June 23, 2000

Today, I am voting to proceed with the issuance of a proposed rule to require special packaging for over-the-counter switched oral prescription drugs. As we know, the regulations of the Poison Prevention Packaging Act require child-resistant packaging of most oral prescription drugs. However, when the Food and Drug Administration allows an oral prescription drug to be sold over-the-counter, child resistant packaging of that drug is no longer required despite the presumption that moving to over-the-counter status will only make these drugs more readily available to consumers and therefore more accessible to children. To me, the lack of the continued requirement of child-resistant packaging for switched oral prescription drugs is counter-intuitive.

In 1973, the FDA issued the rule requiring child-resistant packaging for the class of oral prescription drugs. In doing so, the FDA thus satisfied the statutory finding that special packaging is required to protect children from that class of drugs. Over-the-counter switches did not begin to occur for some years after the FDA issued the 1973 rule and, since 1976, twenty-two oral prescription drugs have been approved for over-the-counter status. There has been no evidence presented to me that the FDA anticipated the trend to approve these switches when they issued the regulation in 1973. Additionally, our staff has presented sufficient indicators that the trend to approve over-the-counter switches of oral prescription drugs will only increase in the future.

Currently, this Commission is required to begin a rulemaking to continue requiring special packaging each time a drug is approved for the switch from oral prescription to over-the-counter status. As it stands, the process is simply not an efficient use of our resources. Clearly, the presumption that the same drug must pose the same hazard to a child, regardless of how it is available, should continue unless otherwise rebutted. The purpose of the recommended Commission rulemaking is to maintain the same allocation of responsibility when drugs are switched from oral prescription to over-the-counter status. A drug manufacturer will still be able to petition the Commission and supply grounds to justify an exemption. This rulemaking makes sense to me.

I strongly recommend that manufacturers of drugs who may be affected by this proposed rule take advantage of the opportunity to comment on this rulemaking during the provided comment period. If there are legitimate reasons why this Commission should not or cannot move forward with this rule then those reasons should be presented to us for our consideration.