structure(s) constructed or rehabilitated with SBA financial assistance.

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Dated: March 23, 1979.

A. Vernon Weaver,
*Administrator.*

[Rev. 6, Amdt. 21]

[FR Doc. 79-11205 Filed 4-10-79; 8:45 am]
BILLING CODE 8025-01-M

## FEDERAL TRADE COMMISSION

### 16 CFR Part 1

### Industry Guidance; Advisory Opinions Rule Amendment

**AGENCY:** Federal Trade Commission.

**ACTION:** Final rule.

**SUMMARY:** This amendment of the agency's advisory opinion procedures seeks to expedite advice and guidance to the public, especially small businesses, about enforcement of the laws and regulations administered by the Commission. The change is intended to clarify §§ 1.1 through 1.4 of the Rules of Practices so as to indicate the circumstances in which Commission or staff advice will be issued. Commission opinions will be issued where the question involves a substantial or novel question, or a proposed merger. In other cases the Commission's staff will respond, with advice or with a statement reflecting present staff enforcement intentions. Such staff advice would be rendered without prejudice to the right of the Commission later to rescind it. The changes also delete the present provision under which advisory opinions may not be rendered with respect to ongoing courses of action.

This change was published for comment on January 8, 1979 (44 FR 1753). No comments were received and no changes have been made from the original proposal.

**DATE:** Effective April 11, 1979.

**FOR FURTHER INFORMATION CONTACT:** Barry R. Rubin, Assistant General Counsel, Federal Trade Commission, Washington, D.C. 20580, (202) 523-3520.

**SUPPLEMENTARY INFORMATION:** Since 1962, the Commission has rendered formal advisory opinions about the legality of proposed courses of action. See 16 CFR § 1.1 *et seq.;* 16 CFR § 15.1 *et seq.*

Under the amendment, the Commission will continue to issue formal opinions where the matter involves a substantial or novel question and there is no clear precedent; where a proposed merger or acquisition is involved; or where the subject matter is of significant public interest. Advice will be given on *both* proposed and current courses of action. The Commission will also continue to advise whether proposed conduct will violate an outstanding cease and desist order under § 3.61 of the Rules of Practice.

In other circumstances, the staff is expressly authorized to render advice. The vast majority of requests from the public are already handled informally by the staff of the Office of General Counsel or the bureaus. In the recent past, the Commission has averaged only about 16 formal opinions per year, about half of these involving compliance with trade regulation rules, other Commission rules, or outstanding cease and desist orders. Not only is informal advice provided by General Counsel staff letters, the bureaus constantly are answering mail and telephone inquiries. Small businesses and others tend to receive the quickest and most helpful advice in this manner. Thus, the proposal reduces to writing what is already routine present practice.

For these reasons, the Commission amends its Rules of Practice, §§ 1.1–1.4, to read as follows:

### Part 1—General Procedures

#### § 1.1 Policy.

(a) Any person, partnership, or corporation may request advice from the Commission with respect to a course of action which the requesting party proposes to pursue. The Commission will consider such requests for advice and inform the requesting party of the Commission's views, where practicable, under the following circumstances.

(1) The matter involves a substantial or novel question of fact of law and there is no clear Commission or court precedent;

(2) A proposed corporate merger or acqusition is involved; or

(3) The subject matter of the request and consequent publication of Commission advice is of significant public interest.

(b) The Commission has authorized its staff to consider all requests for advice and to render advice, where practicable, in those circumstances in which a Commission opinion would not be warranted. Hypothetical questions will not be answered, and a request for advice will ordinarily be considered inappropriate where (1) the same or substantially the same course of action is under investigation or is or has been the subject of a current proceeding involving the Commission or another governmental agency, or (2) an informed opinion cannot be made or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

#### § 1.2 Procedure.

(a) Application. The request for advice or interpretation should be submitted in writing (one original and two copies) to the Secretary of the Commission and should (1) state clearly the question(s) that the applicant wishes resolved; (2) cite the provision of law under which the question arises; and (3) state all facts which the applicant believes to be material. In addition, the identity of the companies and other persons involved should be disclosed. Letters relating to unnamed companies or persons may not be answered. Submittal of additional facts may be requested prior to the rendering of any advice.

(b) Compliance matters. If the request is for advice as to whether the proposed course of action may violate an outstanding order to cease and desist issued by the Commission, such request will be considered as provided for in § 3.61 of these Rules.

#### § 1.3 Advice.

(a) On the basis of the materials submitted, as well as any other information available, and if practicable, the Commission or its staff will inform the requesting party of its views.

(b) Any advice given by the Commission is without prejudice to the right of the Commission to reconsider the questions involved and, where the public interest requires, to rescind or revoke the action. Notice of such rescission or revocation will be given to the requesting party so that he may discontinue the course of action taken pursuant to the Commission's advice. The Commission will not proceed against the requesting party with respect to any action taken in good faith reliance upon the Commission's advice under this section, where all the relevant facts were fully, completely, and accurately presented to the Commission and where such action was promptly discontinued upon notification of rescission or revocation of the Commission's approval.

(c) Advice rendered by the staff is without prejudice to the right of the Commission later to rescind the advice and, where appropriate, to commence an enforcement proceeding.

#### § 1.4 Public disclosure.

Written advice rendered pursuant to this Section and requests therefor,

including names and details, will be placed in the Commission's public record immediately after the requesting party has received the advice, subject to any limitations on public disclosure arising from statutory restrictions, the Commission's rules, and the public interest. A request for confidential treatment of information submitted in connection with the questions should be made separately.

By direction of the Commission dated March 30, 1979.

Carol M. Thomas,
*Secretary.*

[FR Doc. 79-11237 Filed 4-10-79; 8:45 am]
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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1700

### Poison Prevention Packaging; Exemption from Child Resistant Packaging Standards for Anhydrous Cholestyramine in Powder Form

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document the Commission issues a final amendment under the Poison Prevention Packaging Act (PPPA) to exempt anhydrous cholestyramine in powder form from the special packaging requirements imposed by the act. The Commission is taking this action because of the low incidence of accidental ingestions of this drug by children as well as the lack of potential for serious illness or injury from the drug.

**EFFECTIVE DATE:** This amendment is effective April 11, 1979.

**FOR FURTHER INFORMATION CONTACT:** Sandra Eberle, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6400.

**SUPPLEMENTARY INFORMATION:**

#### Background

Regulations issued under the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471-1476) establish child-protection packaging requirements for human oral prescription drugs in order to protect children from serious personal injury or illness resulting from handling, using, or ingesting these substances.

On February 11, 1974 the Commission proposed an exemption from the child-resistant packaging regulation for oral prescription drugs (16 CFR 1700.14(a)(10)), in response to a petition (PP 74-17) from Mead Johnson Laboratories, for anhydrous cholestyramine in powder form (marketed by Mead Johnson as Questran), a chloride salt of a basic anion-exchange resin (39 FR 5197). In proposing the exemption, the Commission also stayed the special packaging regulations for prescription drugs as it applied to cholestyramine pending issuance of a final exemption.

Anhydrous cholestyramine in a powder form, a noneffervescent powder which is intended to be suspended in water or other liquids prior to consumption, is used to lower cholesterol levels in the blood. The Commission proposed the exemption due to the low incidence of accidental ingestions by children as well the lack of potential for serious injury or illness from the drug.

It should be noted that the **Federal Register** document in which the Commission proposed to exempt cholestyramine also included proposed exemptions for several other substances. (39 FR 5197). The final rule contained herein, however, applies only to anhydrous cholestyramine in powder form and does not address the exemptions for these other substances.

#### Response to Comments

Fifteen comments were received by the Commission in response to the proposed exemptions, although only one discussed the specific issue of whether cholestyramine should be exempted. Some of the comments addressed the proposed exemptions of the other drugs listed in the February 11, 1974 **Federal Register** notice; these comments will not be discussed here. Five comments discussed the general issue of whether any exemptions to the special packaging requirements should be granted.

The one comment that dealt specifically with cholestyramine was from the American Academy of Pediatrics' Committee on Drugs, which noted a report stating that overdoses of the drug may cause nausea, diarrhea and constipation. Commission staff reviewed the pharmacology of the drug in regard to these overdose side effects and found that mild and transient constipation was reported to occur more often than nausea and diarrhea. It has also been found that high dosage levels and advanced age appear to predispose individuals to constipation. The Commission notes that these side effects are associated with normal therapy and cannot be viewed as indicative of any potential for serious personal injury or illness in children.

As noted above, five commenters were concerned about exemptions in general. One commenter noted that exemptions should be granted only "with restraint" and that criteria other than toxicological issues should be examined. Two commenters suggested that manufacturers should be required to inform the public, through advertising and product labeling, of which drugs have been exempted and in what amounts. Other commenters envisioned the difficulties pharmacists might face in filling prescriptions for exempted drugs, in particular, in determining what quantities of a drug may be in regular packaging and what quantities require child-protection closures. Other respondents simply opposed any exemptions from the PPPA's requirements, citing the possibility of individual reactions, long term effects, and errors in compounding prescriptions as justification for safety packaging for all oral prescription drugs. Some commenters expressed concern that consumers would be confused over the two categories of drug containers in the home; others felt that non-complying packaging will increase health care costs.

A summary of these comments and the Commission's detailed responses were published in the **Federal Register** on January 31, 1979 (44 FR 6340). In brief, the Commission determined that none of the general comments were convincing as to the point that exempting specific drugs which cannot cause serious personal injury or illness to children from the PPPA's special packaging requirements is unsafe or ill-advised.

#### Injury Data

The Commission bases its decision to issue a final exemption for anhydrous cholestyramine in powder form, in part, on the lack of significant adverse human experience data reported by the National Clearinghouse for Poison Control Centers (NCPCC). During the years 1969-76, no accidental ingestions of cholestyramine by children younger than five years of age were reported to NCPCC. An examination of the Commission's Poison Control Center data during 1976-77 also revealed no accidental ingestions of cholestyramine by children under five years old.

Toxicity data submitted by the petitioner, Mead Johnson Laboratories, show the substance to be relatively safe. No deaths or signs of toxicity in mice were observed during the seven days following oral administration of 10 grams per kilogram of body weight of the drug. Using the 10 kilogram child, this would extrapolate to an extremely