# Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rulemaking prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

### [ 21 CFR Part 130 ]

### OVER-THE-COUNTER (OTC) DRUGS GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

### Notice of Hearing on Tentative Final Order for Antacid Products

In the FEDERAL REGISTER of November 12, 1973 (38 FR 31260), the Commissioner of Food and Drugs, pursuant to 21 CFR 130.301(a)(7), published a tentative final order for over-the-counter (OTC) antacid products.

Interested persons were invited within 30 days to submit written objections and to request an oral hearing before the Commissioner regarding this tentative final monograph. Ten requests for a hearing were received. In accordance with 21 CFR 130.301(a)(8), the Commissioner has scheduled an oral hearing on January 21, 1974 at 1:00 p.m. at the Food and Drug Administration, Conference Room F, 3rd Floor, 5600 Fishers Lane, Rockville, Maryland 20852.

The oral hearing will be limited to the administrative record, which consists of all of the data and information submitted in response to the request for data and information as published in the FEDERAL REGISTER of January 5, 1972 (37 FR 102) and pursuant to procedures for classification of over-the-counter drugs published in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), the minutes of Panel meetings, the Panel report, the proposed order as published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714), the comments submitted in response, and the tentative final order as published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260). The complete administrative record is on public display at the Office of the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, Maryland 20852.

As this is a hearing on the administrative record, any new data or information may be discussed only if such material is first submitted to the Commissioner with a petition to reopen the administrative record to include such material, and the Commissioner grants the petition. Any such petition shall demonstrate good cause why such material could not have been obtained and submitted as part of the comments on the proposed monograph. If such a petition is not granted such material is properly submitted with a petition to amend the monograph pursuant to 21 CFR 130.301(a)(11).

Some of the issues raised by those requesting time to appear at the hearing involve 21 CFR 130.302, which sets forth general conditions for OTC drugs which are generally recognized as safe and effective and are not misbranded. That regulation became effective on December 12, 1973. The Commissioner has decided to hear views on that regulation. If any changes are concluded to be appropriate, a proposal will be published in the FEDERAL REGISTER to amend the regulation.

The time of the oral hearing will be divided according to the issues and the parties who wish to appear concerning the issues. If more than one party is listed after an issue, the parties may divide the time in minutes equally or they may choose a spokesperson(s) to use the allotted time.

| Time in minutes | Issue | Interested party |
|---|---|---|
| 10 | I. Legal status of monograph | Proprietary Association. |
| 10 | II. Effective date of final order | Proprietary Association. |
| 20 | III. Role of pharmacist: Request reference to pharmacists on label. Request third class of drugs. | Warner Chilcott. American Pharmaceutical Association. American Association of Colleges of Pharmacy. New Jersey Pharmaceutical Association. National Association of Retail Druggists. |
| | IV. Monograph issues: | |
| 20 | A. Requests revision of antiflatulant monograph. | ICI America, Inc. |
| 20 | B. Opposes combination of antacid with analgesic. | Health Research Group. |
| 10 | C. Antacid active ingredients. 1. In Vitro test validation is required. | Forest Laboratories, Inc. National Association of Pharmaceutical Manufacturers. |
| 10 | 2. Oppose requirement that each antacid active ingredient must constitute 25 percent of total neutralizing capacity. | Warner Chilcott. National Association of Pharmaceutical Manufacturers. Warner Chilcott. |
| 5 | D. Warnings. 1. Language should not be mandatory. | National Association of Pharmaceutical Manufacturers. |
| 10 | 2. Opposes warning where constipation or laxation occurs in 5 percent of users. | Do. |
| 5 | E. Directions for use should say "as needed". | Proprietary Association. |
| 5 | F. "Ethical labeling" should be changed to "Professional labeling". | National Association of Retail Druggists. |
| 5 | G. Quantitative ingredients should be listed. | American Pharmaceutical Association. |
| 5 | H. Other drug interactions should be listed. | Do. |
| 5 | I. Poison Control Centers should be included in 21 CFR 130.302(g). | American Association of Colleges of Pharmacy. |

At the conclusion of the presentations brief-rebuttal comments will be permitted during the time that remains.

Dated: January 3, 1974.

A. M. SCHMIDT,
*Commissioner of Food and Drugs.*

[FR Doc.74-653 Filed 1-7-74;8:45 am]

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### Social Security Administration

### [ 20 CFR Part 416 ]

[Reg. No. 16]

### SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

### Redeterminations of Eligibility and Plans for Achieving Self-Support

Notice is hereby given, pursuant to the Administrative Procedure Act (5 U.S.C. 553), that the amendments to the regulations set forth in tentative form below are proposed by the Commissioner of Social Security with the approval of the Secretary of Health, Education, and Welfare. Proposed § 416.222 of Subpart B would establish the frequency of redeterminations of eligibility. Proposed § 416.1731 of new Subpart Q provides basic guidelines for the exclusion from the countable income and resources of a blind or disabled individual, of the income and resources necessary to fulfill a plan for achieving self-support.

The rules set forth in the proposed regulations will be applied by the Social Security Administration in order to administer the Supplemental Security Income program during the period from January 1, 1974, when the new program becomes effective, until final regulations are adopted.

Prior to the final adoption of the proposed amendments to the regulations, consideration will be given to any data, views, or arguments pertaining thereto which are submitted in writing in triplicate to the Commissioner of Social Security, Department of Health, Education,