the study requirements need to be changed.

The preclearance requirement was revoked in the September 10, 1968 amendment. The agency concluded at that time that the investigational use of DMSO could be adequately controlled by the imposition, by regulation, of the specific limitations on the investigational use of DMSO. Under those circumstances it was thought that preclearance was no longer necessary for the investigation of DMSO.

In the Federal Register of August 14, 1970 (35 FR 12891), the agency published a requirement that clinical studies for all drugs not be initiated until 30 days after the date the agency receives the IND (21 CFR 312.1(a)(2)). This requirement enables the agency to review IND submissions, including those for DMSO, before the studies are initiated, and thereby assure that the studies are to be conducted in accordance with all the appropriate restrictions. For these reasons, the agency has tentatively concluded that § 250.107 is unnecessary and should be revoked.

The agency's position on the investigational status of DMSO, and concern about the safety of human use of DMSO, is now widely known. If it is concluded that the information concerning DMSO needs further publicizing it will be done in the *Drug Bulletin* and by press release.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701, 52 Stat. 1050–1053 as amended, 1055–1056 as amended (21 U.S.C. 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 250 be amended by revoking § 250.107 *Dimethylsulfoxide (DMSO) preparations; clinical testing and investigational use.*

Interested persons may, on or before November 20, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: September 12, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29016 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 331]

[Docket No. 78N-0263]

Antacid Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the labeling requirements for over-the-counter (OTC) antacid drug products to permit antacids to be labeled for the relief of upset stomach associated with heartburn, sour stomach, and acid indigestion. This action is being taken because the agency has tentatively concluded that the term "upset stomach" is used by consumers to describe symptoms associated with gastric hyperacidity. The agency proposes that this claim be permitted in conjunction with the currently accepted antacid claims.

DATE: Comments by November 20, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued the final order for OTC antacid drug products generally recognized as safe and effective and not misbranded (21 CFR Part 331). In the preamble to the final order, the agency declined to place the term "upset stomach" in Category I as an allowable indication in OTC antacid labeling because the phrase is used by consumers to describe the symptoms relieved by completely different products. The agency advised that to justify the use of the term "upset stomach" in antacid labeling, a manufacturer would need to conduct either a clinical trial to establish that the product is effective in relieving the symptoms described by the consumer as "upset stomach," or a statistically valid consumer survey to determine how the consumer interprets the term "upset stomach."

During the Category III testing period provided for OTC antacid drug products, two firms submitted data in support of petitions to amend § 331.30(a) (21 CFR 331.30(a)) to allow indications other than "heartburn," "sour stomach," and "acid indigestion." Miles Laboratories, Inc. (OTC file No. 31–000192) sought to include the indication "for the symptoms of upset stomach after too much to eat and drink." Warner-Lambert Co. (OTC file No. 31–11370) sought to include the indication "upset stomach" in antacid labeling. In the notice of final classification of Category III antacid ingredients and labeling claims published in the Federal Register of September 5, 1978 (43 FR 39427), the agency announced that the final evaluation of these petitions had been delayed. These petitions have been placed on public display in the office of the Hearing Clerk (address given above).

In support of its petition, Miles Laboratories, Inc., submitted the results of two consumer surveys and a clinical trial. In one consumer survey, conducted in Mexico, five different groups of subjects were asked to complete a questionnaire designed to show the individual symptoms that the subjects used to describe the gastrointestinal discomfort that they experienced during the study. The five groups consisted of normal individuals who served as a control group, normal individuals who were fed a heavy meal, normal individuals who were given a drug that causes gastrointestinal discomfort, hospitalized patients experiencing severe drug-induced gastritis, and hospitalized patients with a variety of gastrointestinal complaints. The stated objective of this study was to characterize a cluster of symptoms resulting from overindulgence in food and drink that was distinguishable from the symptoms produced by other gastrointestinal conditions or drugs. Using statistical methods, investigators, who were unaware of the identity of the individuals completing the questionnaire, were able to classify a high percentage of the survey subjects into the correct experimental groups simply on the basis of the frequency with which the subjects cited certain symptoms in describing their gastrointestinal discomfort. The symptons named by the normal individuals who were fed a heavy meal,

listed in order of frequency of naming, were "fullness," "heartburn," "passing of gas," "stomach ache," "belching," "a rumbling sensation," "thirsty or dry mouth," "sluggishness," "taste repeat," "nausea," and "a bitter or acidic aftertaste." The authors of this study concluded that a sufficiently distinct pattern of symptoms resulting from overindulgence in food and drink exists to permit overindulgence to be distinguished from other causes of gastric discomfort. No information presented in this study demonstrates that the term "upset stomach" was used preferentially by one group over another to describe symptoms of gastrointestinal discomfort.

In the second consumer survey, 143 male subjects who had experienced "upset stomach" at least once in the last 6 months were questioned about the cause of their upset stomach. Of the respondents, 53 percent listed overindulgence in food and drink, and another 27 percent listed overeating alone, as the cause of upset stomach. The survey subjects were also given a list of 33 symptoms, compiled from the symptoms of gastric discomfort listed by participants in the Mexican study described in the preceding paragraph, and were asked to check those that they usually experienced when they had an upset stomach and those for which they took medication. The most commonly checked symptom (72 percent) was a "feeling of fullness." Other symptoms checked by more than half the subjects were "passing of gas," "belching," "rumbling sensation," "mild headache," and "heartburn."

Subjects in the clinical study submitted by Miles Laboratories, Inc., were given a heavy meal accompanied by alcoholic beverages to induce an "upset stomach." The ability of an OTC antacid drug product marketed by Miles to relieve the symptoms of this overindulgence was compared to that of two other products and a placebo. Based on the subjective responses of subjects in this study, the sponsors concluded that the Miles product was superior to the placebo and to the other products in relieving 9 of the 10 upset stomach symptoms that constitute the overindulgence syndrome.

On the basis of the results of these consumer surveys, Miles Laboratories, Inc., contends that the symptoms of gastrointestinal discomfort induced by overeating or drinking too much are distinguishable from GI symptoms arising from other causes. Miles has not attempted, however, to determine whether consumers use the term "upset stomach" to describe symptoms resulting from causes other than overindulgence.

The agency has concluded that the data submitted by Miles Laboratories, Inc., do not definitively establish a link between overindulgence in food and drink and hyperacidity. It may be, as Miles claims, that the cluster of symptoms referred to as "upset stomach" is, in fact, caused by overindulgence in food and drink. That is not the issue here. Part 331 includes only those ingredients that are generally recognized as safe and effective for relieving symptoms known to be associated with gastric hyperacidity, specifically the symptoms of heartburn, sour stomach, and acid indigestion; and Miles has failed to demonstrate that overindulgence is related to or produces gastric hyperacidity. Accordingly, FDA is denying the Miles petition to amend Part 331 to include the claim "for the symptoms of upset stomach after too much to eat and drink." Even if Miles had shown that the symtoms that consumers call "upset stomach" are due to overindulgence in food and drink, that claim may not properly be included in this monograph, in the absence of proof that overindulgence produces gastric hyperacidity.

FDA recognizes, however, that terms such as "heartburn" may also be used by consumers to describe gastrointestinal distress resulting from other causes, such as overindulgence in food and drink; and that antacid ingredients may also be effective in relieving some of the symptoms referred to by those terms. The agency has referred the review of ingredients for the relief of gastrointestinal distress from causes other than gastric hyperacidity to the OTC Advisory Review Panel on Miscellaneous Internal Drug Products. Among ingredients to be reviewed by that Panel are those that are claimed to relieve the symptoms resulting from overindulgence in food and drink. Therefore, the agency believes that it is proper for the Panel to review the data contained in the Miles Laboratories, Inc., petition and to recommend appropriate labeling indications for such products. The agency will make no decision regarding the use of this claim for categories of OTC drug products other than antacids until the OTC Advisory Review Panel on Miscellaneous Internal Drug Products has reviewed the data and FDA has published its conclusions in the **Federal Register.**

In support of its petition, the Warner-Lambert Co. submitted the results of a combined patient survey and clinical study. Approximately half of the patients surveyed used one or more of the three approved antacid claims, i.e., "heartburn," "sour stomach," or "acid indigestion," to describe their "upset stomach." More than 80 percent of the subjects described their condition by terms that included at least one of the following symptoms: "heartburn," "acid indigestion," or "gas" (or terms judged by the sponsor to be synonyms of these terms).

The agency is denying the Warner-Lambert petition to amend Part 331 to include the indication "upset stomach" when it is unqualified by any further descriptive language for two reasons. First, the petition did not demonstrate that the term "upset stomach," by itself, is understood by consumers to be related exclusively to hyperacidity as described by the terms for describing symptoms that are currently allowed as indications in the labeling of OTC antacid drug products. Second, the clinical study submitted by Warner-Lambert indicated that its antacid product was no more effective than a placebo in relieving those symptoms of upset stomach described by the test subjects.

Although the term "Upset stomach" by itself is inappropriate as an indication in the labeling of OTC antacid drug products, the agency acknowledges that consumers frequently use the term "upset stomach" to describe sysmptoms associate with gastric hyperacidity such as "heartburn," "sour stomach," and "acid indigestion." As reported by one of the petitioners, half the subjects in one study used at least one of these symptoms to describe "Upset stomach." In such specific cases, the individual may safely use an OTC antacid drug product to relieve effectively what is regarded as an "upset stomach." The agency believes that better consumer understanding of the use of OTC antacid drug products can be expected by providing for an additional antacid claim that includes the familiar term "upset stomach." Therefore, FDA proposes on its own initiative to amend the antacid monograph to permit OTC antacid drug products to be labeled for the relief of upset stomach associated with heartburn, sour stomach, and acid indigestion. Manufacturers of OTC antacid drug products may adopt this labeling as of the date of publication of this proposal, subject to the possibility that FDA may change its position, or alter the wording of the claim, as a result of comments filed in response to this proposal.

The agency is also proposing to amend § 331.30 to include a "Statement

of Identity" paragraph to conform with the format of other recently proposed monograph.

FDA has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)), and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238, 239, 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 331 be amended in § 331.30 by revising paragraph (a); redesignating existing paragraphs (b), (c), (d), and (e) as (c), (d), (e), and (f), respectively; and adding new paragraph (b) to read as follows:

§ 331.30 Labeling of antacid products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antacid."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following:

(1) "For the relief of" (optional, "any or all of the following:") "heartburn," "sour stomach," "acid indigestion"; and/or

(2) "For the relief of upset stomach associated with" (optional, "any or all of the following:") "heartburn," "sour stomach," "acid indigestion."

* * * * *

Interested persons may, on or before November 20, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: September 12, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29015 Filed 9-20-79; 8:45 am]

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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

[29 CFR Part 1613]

Extension or Retroactivity for Allegations of Handicap Discrimination

AGENCY: Equal; Employment Opportunity Commission.

ACTION: Proposed rulemaking.

SUMMARY: This amendment will require agencies to process certain allegations of handicap discrimination which they are not required to process under current regulations. Specifically, the amendment would require an agency to process an allegation which was the basis of a grievance or a discrimination complaint which was pending with the agency, the Commission or in a Federal Court on April 10, 1978 regardless of whether the acts or personnel actions occurred prior to the one year period identified by 29 CFR 1613.709(b), formerly 5 CFR 713.709(b), 43 FR 12295.

DATE: Comments must be received on or before November 20, 1979.

ADDRESS: Comments should be directed to: Marie Wilson, Office of the Executive Secretariat, Room 46750, U.S. Equal Employment Opportunity Commission, 2401 E Street, Northwest, Washington, D.C. 20506, (202) 634–6750.

FOR FURTHER INFORMATION CONTACT: John Rayburn, Director, Technical Guidance Division, Office of Field Services, U.S. Equal Employment Opportunity Commission, 2401 E Street, Northwest, Washington, D.C. 20506, (202) 634–6863.

SUPPLEMENTARY INFORMATION: Section 713.709(b) of the Civil Service Commission regulations required processing of complaints of handicap discrimination which were based on actions that occurred during the one year period prior to the effective date of the regulations (April 10, 1978). The Civil Service Commission reviewed and evaluated the suggestion that the procedure be made available to persons alleging handicap discrimination based on acts of personnel actions that occurred on or after September 26, 1973 (date of Rehabilitation Act). After considering the administrative implications of such an extended retroactivity period, the Civil Service Commission determined that the proposal was not feasible and decided to establish the one (1) year period. However, in reexamining the issue, the Civil Service Commission found substantial basis for requiring agencies to process allegations of handicap discrimination which were pending and therefore current in the administrative or judicial process on the effective date of the regulations (April 10, 1978), even when the action giving rise to the allegations occurred prior to the one year retroactivity period provided by 5 CFR 713.709(b), 43 FR 12295.

A proposed amendment of this kind was pending on January 1, 1979, when the Equal Employment Opportunity Commission, pursuant to Reorganization Plan No. 1 of 1978, assumed jurisdiction over federal EEO responsibilities and adopted as its own at 29 CFR Part 1613 the Civil Service Commission regulations on complaint processing. See 43 FR 60901. The EEOC reviewed and decided to adopt the Civil Service Commission's proposal, adding language to clarify that it is the responsibility of the claimant to initiate the complaint and providing a time period within which such action must be taken.

The Commission recognizes the possibility that the matters pending on April 10, 1978, may have been subsequently addressed and disposed on their merits in accordance with the complaint procedures adopted on that date. In such a case an agency could reject a complaint in conformity with 29 CFR 1613.215 (former 5 CFR 713.215, 43 FR 60901). The complainant who believes the rejection was inappropriate could appeal to the Commission under 29 CFR 1613.231(a)(1).

Accordingly, it is proposed to amend 29 CFR Part 1613 (formerly 5 CFR Part 713) to add a new § 1613.709(c) as set out below:

§ 1613.709 Coverage

* * * * *

(c) Notwithstanding the provision of paragraph (b) of this section, a complainant may request an agency to process allegations of handicap discrimination which had been filed as a discrimination complaint or as a grievance, and were pending with the agency, the Civil Service Commission or in a Federal Court on April 10, 1978. Such requests for processing of allegations of handicap discrimination must be brought to the attention of the agency EEO counselor not later than 180 days from the publication of this