DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 331

[Docket No. 79N-0433]

Delegations of Authority and Organization; Antacid Drug Products for Over-the-Counter Human Use; Amendment of a Monograph

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the administration procedures by which persons might request and be granted a modification of the in vitro test for over-the-counter (OTC) antacid drug products. This document also contains a redelegation of authority to FDA's National Center for Drugs and Biologics (NCDB) to grant or deny petitions for a test modification. This action is taken to make these procedures conform to the agency's current administrative regulations and to clarify the procedures for submitting such a request.

EFFECTIVE DATE: September 30, 1982.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 27, 1980 (45 FR 35349), FDA proposed to amend the OTC antacid monograph (21 CFR Part 331) to update and to clarify administrative procedures by which persons might request and be granted a modification of the in vitro testing procedures for OTC antacid drug products. Interested persons were invited to file written comments regarding this proposal by July 28, 1980. No comments were received in response to the proposal. Therefore, the final regulation is being issued in the form in which it was proposed. Also, as mentioned in the proposal, FDA is making a conforming amendment to the delegation of authority regulation.

Administrative Procedures for Requests for Modification of the In Vitro Test for OTC Antacid Drug Products

As stated in the May 27, 1980 proposal, the agency has determined that any request for, and the data in support of, proposed modifications of the in vitro testing procedures for OTC antacid drug products should be submitted to the Dockets Management Branch (HFA-305) in the form of a citizen petition under the procedures established in the agency's general administrative practices and procedures regulations (§ 10.30 (21 CFR 10.30)). Consistent with the procedures under § 10.30, the agency will notify the petitioner in writing whether the petition is granted or denied. This new procedure is in keeping with the public nature of the OTC drug review. Similarly, any decisions regarding such a petition will be placed on public display in the Dockets Management Branch. Section 331.29 of the monograph for OTC antacid drug products is being amended to clarify this procedure.

In the May 27, 1980 proposal, the agency also stated its intention to redelegate the authority to grant or deny petitions seeking modification of the in vitro testing procedures in 21 CFR Part 331 from the Commissioner of Food and Drugs to the Director and Deputy Director of the Division of OTC Drug Evaluation in the Bureau of Drugs. (In a subsequent notice published in the **Federal Register** of June 22, 1982 (47 FR 26913), FDA announced the merger of the Bureaus of Drugs and Biologics into the National Center for Drugs and Biologics (NCDB). Under this merger, the former Bureau of Drugs is now a part of NCDB). Section 5.31 (21 CFR 5.31) is revised to include the proposed redelegation as well as a redelegation to the Director NCDB, the Director, Deputy Director, and Associate Director for Drug Monographs, Office of Drugs, NCDB. Further redelegation of the authority delegated is not authorized.

The agency has examined the economic consequences of this rulemaking and has determined that it does not require a Regulatory Impact Analysis as specified in Executive Order 12291. This final rule does not impose any new burden on any person, because it merely updates and clarifies the administrative procedures by which persons might request a modification of the in vitro testing procedures for OTC antacid drug products. Therefore, the agency concludes that the final rule is not a "major" rule as defined in section 1(b) of Executive Order 12291. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

21 CFR Part 331

OTC drugs, Antacids.

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Parts 5 and 331 are amended as follows:

1. Part 5 is amended by redesignating the existing text as paragraph (a) (1) and (2) and adding new paragraph (b); as revised, § 5.31 reads as follows:

§ 5.31 Petitions under Part 10.

(a) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs and to amend any effective date established under § 201.59.

(1) The Director of the National Center for Drugs and Biologics (NCDB).

(2) For drugs assigned to their respective office, the Director and Deputy Director of the Office of New Drug Evaluation and the Director and Deputy Director of the Office of Biologics, NCDB.

(b) The Director, NCDB, the Director, Deputy Director, the Associate Director for Drug Monographs, and the Director and Deputy Director of the Division of OTC Drug Evaluation of the Office of Drugs, NCDB are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting in vitro test modifications under § 331.29 of this chapter.

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

2. Part 331 is amended by revising § 331.29 to read as follows:

§ 331.29 Test modifications.

The formulation or mode of administration of certain products may require modification of this in vitro test. Any proposed modification and the data to support it shall be submitted as a petition under the rules established in § 10.30 of this chapter. All information submitted will be subject to the

disclosure rules in Part 20 of this chapter.

(Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Effective date: This regulation is effective September 30, 1982.

Dated: August 9, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-23777 Filed 8-30-82; 8:45 am]

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21 CFR Part 331

[Docket No. 78N-0433]

Antacid Drug Products for Over-the-Counter Human Use; Labeling

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the labeling provisions for over-the-counter (OTC) antacid drug products to permit the use of the term "upset stomach." The Food and Drug Administration (FDA) is taking this action because it has concluded that consumers use the term "upset stomach" to describe symptoms associated with gastric hyperacidity. In addition, FDA is amending the monograph for OTC antacid drug products to include a "Statement of Identity" paragraph. The agency is taking this action after considering public comments on the proposed rule. This final rule is part of FDA's ongoing review of OTC drug products.

EFFECTIVE DATE: The effective date of the regulation is September 30, 1982. OTC antacid drug products complying with the labeling proposed in the September 21, 1979 proposal may continue to be introduced into interstate commerce until August 31, 1983.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 1979 (44 FR 54731), FDA proposed to amend the antacid monograph (21 CFR Part 331) to permit OTC antacid drug products to be labeled for the relief of upset stomach associated with heartburn, sour stomach, and acid indigestion. The agency also proposed to amend § 331.30 (21 CFR 331.30) to include a "Statement of Identity" paragraph to conform with the format of other recently proposed OTC drug monographs.

Interested persons were invited to file written comments regarding this proposal on or before November 20, 1979. In response to the proposed rule, comments were received from three manufacturers and one trade association.

This final rule contains the agency's decision to amend the labeling requirements for OTC antacid drug products to permit antacid drug products to be labeled for relief of upset stomach associated with heartburn, sour stomach, and acid indigestion, and to amend § 331.30 to include a "Statement of Identity" paragraph.

A. The Agency's Conclusions on the Comments

1. Several comments agreed with the agency's proposal to permit OTC antacids to be labeled "for the relief of upset stomach associated with heartburn, sour stomach, and/or acid indigestion." One comment added that the proposed amendment would make the approved indications more comprehensible to consumers.

2. A comment contended that OTC monographs issued under the OTC drug review process are interpretive, as opposed to substantive, regulations. The comment referred to previous comments regarding this issue, dated March 4, 1972, on the Proposed Procedural Regulations Governing the OTC Review, and comments dated June 4, 1973, on the Proposed Antacid Monograph.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final order for antacid products, published in the **Federal Register** of November 12, 1973 (38 FR 31260), and FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v. *Weinberger,* 512 F. 2d 688, 696–98 (2d Cir. 1975); *National Association of Pharmaceutical Manufacturers* v. *FDA,* 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd,* 637 F. 2d 887 (2d Cir. 1981).

3. One comment argued that labeling terminology which is truthful, accurate, nonmisleading, and intelligible to the consumer may not legally be prohibited by the promulgation of OTC drug monographs purporting to contain exclusive lists from which OTC labeling pertaining to indications for use must be drawn. The comment also incorporated by reference similar comments submitted on November 22, 1978, on the Proposed Establishment of a Monograph for OTC Sunscreen Drug Products.

Since the inception of the OTC drug review, the agency has maintained that a monograph describing the conditions under which an OTC drug will be generally recognized as safe and effective and not misbranded must include both specific active ingredients and specific labeling. (This policy has become known as the "exclusivity rule.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review literally exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or, as in the case of the present document, through petitions to amend monographs under 21 CFR 330.10(a)(12).

During the course of the review, FDA's position on the "exclusivity rule" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. To assist the agency in resolving this issue, FDA plans to conduct an open public forum on September 29, 1982 where all interested parties can present their views. The forum will be a legislative type administrative hearing under 21 CFR Part 15 that will be held in response to a request for a hearing on the tentative final monograph for nighttime sleep-aids (published in the **Federal Register** of June 13, 1978; 43 FR 25544). Details of the hearing were announced in a notice published in the **Federal Register** of July 2, 1982 (47 FR 29002). In proposed, tentative final, and final monographs (including amendments to final monographs) that are issued in the meantime, the agency will continue to state its longstanding policy.

4. A comment stated that proposed § 331.30(b) (1) and (2) could be interpreted to require literal repetition of the terms "heartburn," "acid indigestion," and/or "sour stomach" when used in connection with the term