DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 332

[Docket No. 87N-0053]

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

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the monograph for over-the-counter (OTC) antiflatulent drug products by adding a statement of identity section to conform to the format of other OTC drug final monographs and by revising the indications for use to include additional descriptive terms. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on the advance notice of proposed rulemaking for OTC digestive aid drug products that was based on those recommendations. The agency's proposed concerning OTC digestive aid drug products is being published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments or objections by March 29, 1988.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antiflatulent drug products (21 CFR Part 332).

In the **Federal Register** of January 5, 1982 (47 FR 454), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)) an advance notice of proposed rulemaking to establish a monograph for OTC digestive aid drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel) which was the advisory review panel responsible for evaluating data on this drug class. Interested persons were invited to submit comments by April 5, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by May 5, 1982.

In a notice published in the **Federal Register** of March 30, 1982 (47 FR 13385), the agency advised that it had extended the comment period until June 4, 1982, and the reply comment period to July 5, 1982, on the advance notice of proposed rulemaking for OTC digestive aid drug products to allow for consideration of additional data and information.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In the tentative final monograph (proposed rule) to establish Subpart D of Part 357 (21 CFR Part 357, Subpart D), published elsewhere in this issue of the **Federal Register**, FDA states for the first time its position on the establishment of a monograph for OTC digestive aid drug products. In reviewing the Panel's recommendations on OTC digestive aid drug products together with the data and comments submitted in response to the advance of proposed rulemaking on OTC digestive aid drug products, the agency recognized that there is significant overlap between the rulemaking on OTC digestive aid drug products and other rulemakings in the OTC drug review. As discussed in comment seven of the tentative final monograph for OTC digestive aid drug products, the agency has reviewed and evaluated the available data and information and has determined that the terms "bloating," "pressure," "fullness," and "stuffed feeling" are appropriate for inclusion in the antiflatulent monograph to describe the symptoms of gas.

In developing the antiflatulent monograph, the agency relied on the results of two double-blind studies (Refs. 1 and 2) which demonstrated the effectiveness of simethicone in relieving symptoms of upper gastrointestinal distress. (See 38 FR 31266.) In both studies the symptoms described as "bloating," "fullness," "pressure," and "stuffed feeling" were among those evaluated. In both studies, simethicone was demonstrated to be effective for relieving these symptoms.

In addition, the results of a consumer survey (Ref. 3) indicate that the terms "bloating," "pressure," "stuffed feeling" and "fullness" are very meaningful to and used by consumers in describing what is commonly, if not accurately, referred to as "gas." Based on these data, the agency is therefore proposing to amend the antiflatulent monograph by adding an additional indications statement to read as follows: (Select one of the following: "Alleviates" or "Relieves") (select one or more of the following: "bloating," "pressure," "fullness," or "stuffed feeling") "commonly referred to as gas."

Additionally, the agency is proposing to amend the antiflatulent monograph to include a "statement of identity" section to conform with the format of other final OTC drug monographs. The agency believes that the term "antigas" is an appropriate alternative statement of identity to the term "antiflatulent" provided there are no statements elsewhere in the labeling implying that the symptoms are caused by the presence of excess gas. For example, phrases such as "antigas formulation relieves gas trapped in the intestine" or "for gas pain" would be considered inappropriate. The agency has also slightly modified the existing indication to conform with the newly proposed indication.

References

(1) Kasich, A., "A Summary of a Double-Blind Study Comparing the Effectiveness of Simethicone and Placebo in the Relief of Symptoms of Functional Disease of the Upper Gastrointestinal Tract," copy of unpublished study included in OTC Volume 17GTFM.

(2) "A Summary of the Double-Blind Study of the Effectiveness of Simethicone in Relieving the Symptoms of Acute Upper Gastrointestinal Distress," copy of unpublished study included in OTC Volume 17GTFM.

(3) Petition from Plough, Inc., dated May 18, 1976, on file under Docket No. 76P-0218, Dockets Management Branch.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antiflatulent drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a

substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antiflatulent drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency has determined that under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before March 29, 1988, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments or objections on the proposed regulation. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on March 29, 1988. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 332

Labeling, Over-the-counter drugs, Antiflatulent drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 332 as follows:

PART 332—ANTIFLATULENT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 332 is revised to read as follows:

Authority: 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); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

Subpart C—[Removed]

2. In Part 332, "Subpart C—[Reserved]" is removed.

3. In Part 332, "Subpart D—Labeling" (consisting of §§ 332.30–332.31) is redesignated as "Subpart C—Labeling" and § 332.30 is amended by redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), by adding new paragraph (a), and by revising new paragraph (b) to read as follows:

Subpart C—Labeling

§ 332.30 Labeling of antiflatulent drug 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 "antiflatulent," "antigas," or "antiflatulent (antigas)."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the Act relating to misbranding and the prohibition in section 301(d) of the Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Act.

(1) (Select one of the following: "Alleviates" or "Relieves") "the symptoms referred to as gas."

(2) (Select one of the following: "Alleviates" or "Relieves") (select one or more of the the following: "bloating," "pressure," "fullness," or "stuffed feeling") "commonly referred to as gas."

* * * * *

Dated: October 30, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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