DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 85N-0554]

Labeling Requirements for Over-the-Counter Drugs; Proposed Amendment of Statement of Identity Requirements

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the labeling requirements for over-the-counter (OTC) drugs in § 201.61(b) [21 CFR 201.61(b)] as follows: (1) To clarify that the statement of identity requirements apply to both single active ingredients and combinations of active ingredients, and (2) to state that OTC drug monographs established under Part 330 [21 CFR Part 330] are the source of the statement of identity of an OTC drug, unless otherwise stated in an approved new drug application, or unless there is no applicable monograph.

DATES: Written comments by June 16, 1986. Written comments on the agency's economic impact determination may be submitted on or before August 15, 1986.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James P. Cobb, Center for Drugs and Biologics (HFN-211), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8006.

SUPPLEMENTARY INFORMATION: The existing labeling requirements in § 201.61(b) establish different types of information that must be provided in the statement of identity of an OTC drug, depending on whether or not the OTC drug has an established name. If an OTC drug has an established name, the statement of identity is the established name of the drug followed by a statement of the general pharmacological category(ies) or the principal intended action(s) of the drug. If an OTC drug does not have an established name, whether or not it contains a single active ingredient or a combination of active ingredients, then the statement of identity is only a statement of the general pharmacological category(ies) or the principal intended action(s) of the drug. Existing § 201.61(b) does not, however, clearly describe how the statement of identity for a combination of OTC active ingredients without an established name is determined. For example, existing § 201.61(b) uses the term "mixture" in stating the requirements even though this term is not defined. In the past, the agency has interpreted the term "mixture" as referring to a drug composed of a combination of active ingredients. In order to remove this ambiguity from the regulation, the agency is proposing that the term "mixture" be deleted and paragraph (b) of § 201.61 be revised to refer clearly to "combinations" of active ingredients.

Existing § 201.61(b) also requires as part of a drug's statement of identity a statement of the general pharmacological category(ies) or the principal intended action(s) of the drug. To clarify what is intended by this requirement, FDA is proposing to amend § 201.61(b) to provide that such statements of general pharmacological category(ies) or principal intended action(s) are those identified in the applicable OTC drug monograph(s) that are established under Part 330, unless otherwise stated in an approved new drug application or unless there is no applicable monograph. The agency is therefore proposing to delete from existing § 201.61(b) the examples of terms describing general pharmacological category(ies) or principal intended action(s), i.e., "antacid," "analgesic," "decongestant," and "antihistaminic."

The agency is also proposing to delete the following sentence in existing § 201.61(b): "The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part." This requirement is not relevant to an OTC drug's statement of identity.

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 statement of identity labeling of OTC 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 statement of identity labeling of OTC 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 invites public comment regarding any substantial or significant economic impact that this rulemaking would have on labeling of statement of identity of OTC drug products. Types of impact may include. but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on the labeling of the statement of identity of OTC drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on the labeling of the statement of identity of OTC drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(a)(11) (April 26, 1985; 50 FR 16636) 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 June 16, 1986, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before August 15, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests 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, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register.**

List of Subjects in 21 CFR Part 201

Drugs, Labeling.

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 201, to read as follows:

PART 201—[AMENDED]

1. The authority citation for 21 CFR Part 201 continues to read as follows:

Authority: Secs. 502, 505, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended (21 U.S.C. 352, 355, and 371); 21 CFR 5.10, 5.11.

2. In § 201.61, paragraph (b) is revised to read as follows:

§ 201.61 Statement of identity.

* * * * *

(b) The statement of identity for a drug composed of a single active ingredient shall be the statement of identity established for that ingredient in the statement of identity section of the applicable OTC drug monograph established under Part 330 of this chapter, unless otherwise stated in an approved new drug application. The statement of identity for a drug composed of a combination of active ingredients shall be the established name of the combination, if there is any, followed by the statement of the general pharmacological category(ies)/principal intended action(s) of each ingredient as identified in the statement of identity section of the applicable OTC drug monographs established under Part 330 of this chapter, unless otherwise stated in an approved new drug application. In either case, if the drug does not have an established name or if there is no monograph established under Part 330 of this chapter, then the statement of identity shall consist only of a prominent and conspicuous statement of the general pharmacological category(ies) or the principal intended action(s) of each ingredient. The statement of identity shall be placed in direct conjunction with the most prominent display of the proprietary name or designation of the drug.

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Dated: March 26, 1986.

M.D. Kinslow,

Acting Associate Commissioner for Regulatory Affairs.

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