

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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[Docket No. 01D-0005]

**Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products;  
Updating Labeling in ANDA's; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's." This draft guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products marketed under abbreviated new drug applications (ANDA's) and manufacturers of reference listed drugs (RLD's) to implement the agency's regulation on standardized content and format requirements for the labeling of OTC drug products.

**DATES:** Submit written comments on the draft guidance for industry by [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** Copies of the draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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**FOR FURTHER INFORMATION CONTACT:** Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Labeling OTC Human Drug Products; Updating Labeling in ANDA’s.” This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the recently issued final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products. This rule is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. This new format will require revision of all existing labeling.

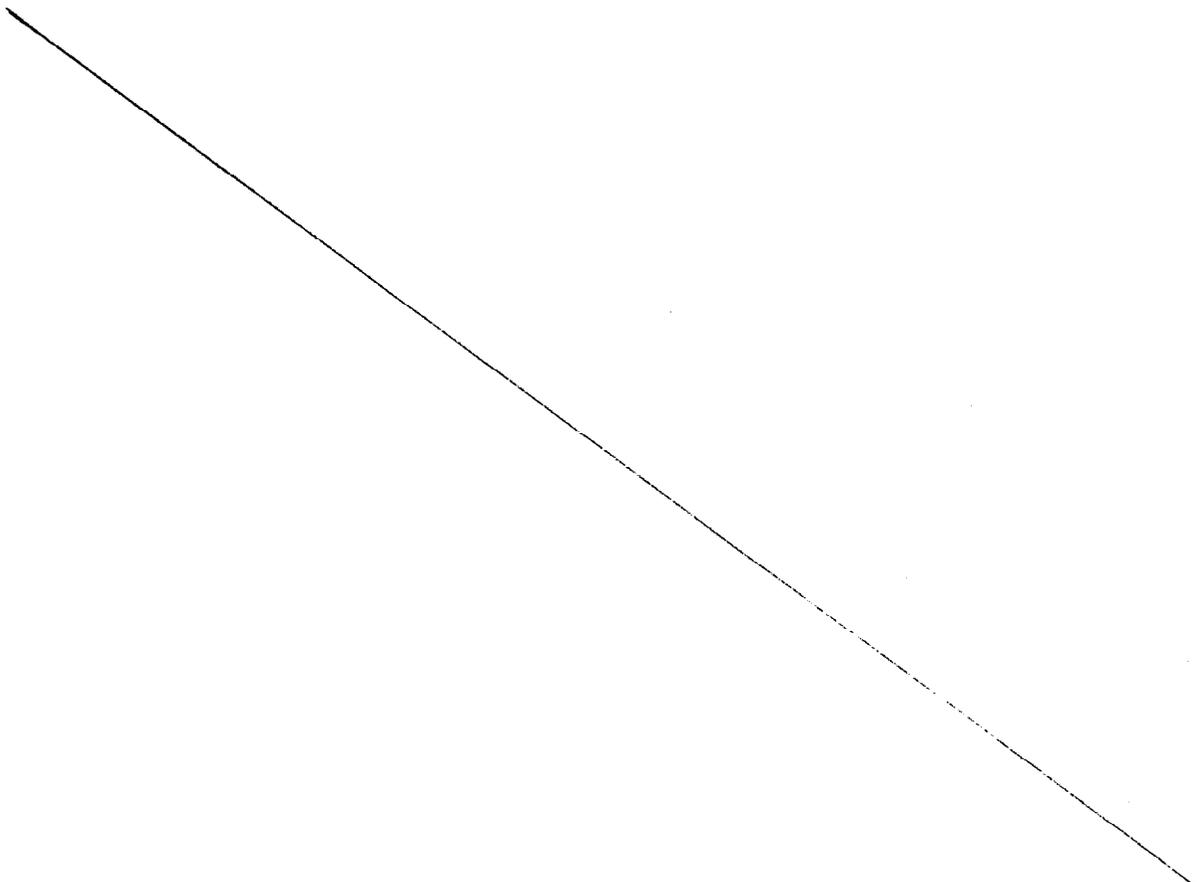
Following issuance of the final rule, the agency received several inquiries from manufacturers of generic OTC drug products seeking guidance on whether they may convert products to the new labeling format before the applicable innovator (or RLD) product revises its labeling. This guidance addresses those inquiries.

Generally, the agency believes manufacturers of generic OTC drug products (i.e., products marketed under ANDA’s) need not wait to implement the new labeling format until after the RLD holder has submitted its labeling. This guidance is intended to facilitate the updating of labeling in ANDA’s to meet the new OTC drug products format requirement. Accordingly, the agency has developed labeling examples as guidance for manufacturers to follow. Two such labeling

examples are attached to the draft guidance. The additional labeling examples that the agency proposes to develop will be made available for review in this docket and at the Internet site referenced in this draft guidance before the close of the comment period.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on updating labeling in ANDA's consistent with the new OTC drug products standardized labeling content and format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may, on or before [*insert date 60 days after date of publication in the Federal Register*], submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals



may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 2001  
February 8, 2001

*Ann M. Witt*

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Ann M. Witt  
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL  
*Katherine Oliver*

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