

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01D-0005]

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Certifier REGINA GEDESMA

**Guidance for Industry on Labeling Over-the-Counter Human Drug Products—Updating Labeling in Reference Listed Drugs and Abbreviated New Drug Applications; 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 guidance for industry entitled “Labeling OTC Human Drug Products—Updating Labeling in RLDs and ANDAs.” The guidance is intended to assist manufacturers of over-the-counter (OTC) reference listed drugs (RLDs) and manufacturers, packers, and distributors of OTC drug products marketed under abbreviated new drug applications (ANDAs) to implement the agency’s regulation on standardized content and format requirements for the labeling of these products.

**DATES:** The guidance for industry is effective [*insert date of publication in the Federal Register*]. Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), 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 requests. Submit written comments on the guidance to the Dockets

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Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Labeling OTC Human Drug Products—Updating Labeling in RLDs and ANDAs.” This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final regulation establishing standardized content and format requirements for the labeling of all OTC drug products. When finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final regulation.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final regulation establishing standardized content and format requirements for the labeling of OTC drug products. The regulation is codified at § 201.66 (21 CFR 201.66). It 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 requires manufacturers to present OTC drug product labeling information in a

prescribed order and format. This new format will require revision of all existing labeling.

Following issuance of the final regulation, the agency received several inquiries from manufacturers of generic OTC drug products seeking guidance on whether they should convert products to the new labeling format before the manufacturers of the applicable innovator (or RLD) products revise their labeling. To address those inquiries, in the **Federal Register** of February 22, 2001 (66 FR 11174), FDA published a notice announcing the availability of a draft guidance entitled “Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDAs,” which included draft recommendations about how manufacturers of OTC drug products marketed under ANDAs and manufacturers of the RLD products could implement the agency’s new regulations for the labeling of OTC drug products. The draft guidance contained a series of labeling examples that manufacturers could use when revising their product labeling to the new format. The notice invited interested persons to submit comments on the draft guidance by April 23, 2001.

FDA received several comments regarding the February 22, 2001, draft guidance and, in response, the agency has made some clarifying changes in the final version of the guidance. Specifically, the agency is providing guidance on its general implementation expectations, the use of agency recommended labeling examples (manufacturers of RLDs who use these do not need agency preapproval), submission of new labeling in an annual report or preapproval supplement, and deferral requests. The agency is also announcing that it intends to exercise its enforcement discretion by giving manufacturers of generic OTC drug products a grace period to comply with the new format requirements of § 201.66. This grace period commenced on May 16, 2002, for

most OTC ANDAs and shall continue until the agency posts on the Internet the approved, updated labeling for an ANDA holder's applicable RLD. At that time, the ANDA holder should revise its labeling. (See the agency's May 2000 guidance for industry entitled "Revising ANDA Labeling Following Revision of the RLD Labeling.")

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on updating labeling in ANDAs consistent with the new standardized labeling content and format required for OTC drug products. 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.

## **II. Comments**

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). 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 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> and <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 10/10/02  
October 10, 2002.



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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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