

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-26475 Filed 10-17-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0428]

Draft "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components" dated October 2002. The draft guidance document recognizes the "Circular of Information for the Use of Human Blood and Blood Components" (the circular) dated July 2002 as acceptable for use by manufacturers of blood and blood components intended for transfusion. The circular will assist those manufacturers in complying with the labeling requirements under FDA regulations.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 17, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance and the Circular to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The documents may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components" dated October 2002. The draft guidance document recognizes that the circular dated July 2002 meets the labeling requirements in § 606.122 (21 CFR 606.122), and therefore is acceptable for use by manufacturers of blood and blood components intended for transfusion that are subject to U.S. statutes and regulations.

The requirements under § 606.122 specify that an instruction circular must be available for distribution with blood and blood components intended for transfusion, and that the information in the instruction circular must include adequate instructions for use. The circular will assist manufacturers of blood and blood components intended for transfusion in complying with the labeling requirements under § 606.122. The circular was prepared jointly by the American Association of Blood Banks, America's Blood Centers and the American National Red Cross. A copy of the circular is in the draft guidance document.

This draft guidance document is being issued in accordance with FDA's good guidance practices regulation (21 CFR

10.115). The draft guidance document represents the agency's current thinking on this topic. 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 approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document 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 draft guidance document and the circular at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>. The circular may also be obtained at www.aabb.org.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-26612 Filed 10-17-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0005]

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.

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 October 18, 2002. 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 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

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Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Professions and Nurse Education Special Emphasis Panel; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Health Professions and Nurse Education Special Emphasis Panel meetings. Part of the meeting will be open to the public. The rest of the meeting will be closed to the public. The closing is in accordance with the provision set forth in section 552(b)(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92-463.

Name: Dental Public Health.