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persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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

BILLING CODE 4160–01–S

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 The draft guidance document recognizes the ''Circular of Information for the Use of Human Blood and Blood Components'' (the circular) dated July 2002 as acceptable for use by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DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 17, 2002.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ADDRESSES: Submit written requests for single copies of the draft guidance and the Circular to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and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.

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BILLING CODE 4160–01–S

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