

DMB

Display Date 12.9.03

Publication Date 12.10.03

Certifier G. Luntz

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2002D-0428]

**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 document entitled "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components" dated December 2003. The 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 manufacturers in complying with the labeling requirements under FDA regulations. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2002.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance 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 guidance 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 guidance document.

Submit written comments on the guidance to the Division of Dockets Management (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 document entitled “Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components” dated December 2003. The guidance recognizes that the circular dated July 2002 meets the labeling requirements in § 606.122 (21 CFR 606.122) and is acceptable for use by manufacturers of blood and blood components intended for transfusion that are subject to U.S. statutes and regulations. 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 included as an attachment in the guidance document. The guidance announced in this notice finalizes the draft guidance of the same title, dated October 2002 (67 FR 64402, October 18, 2002).

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance document represents the

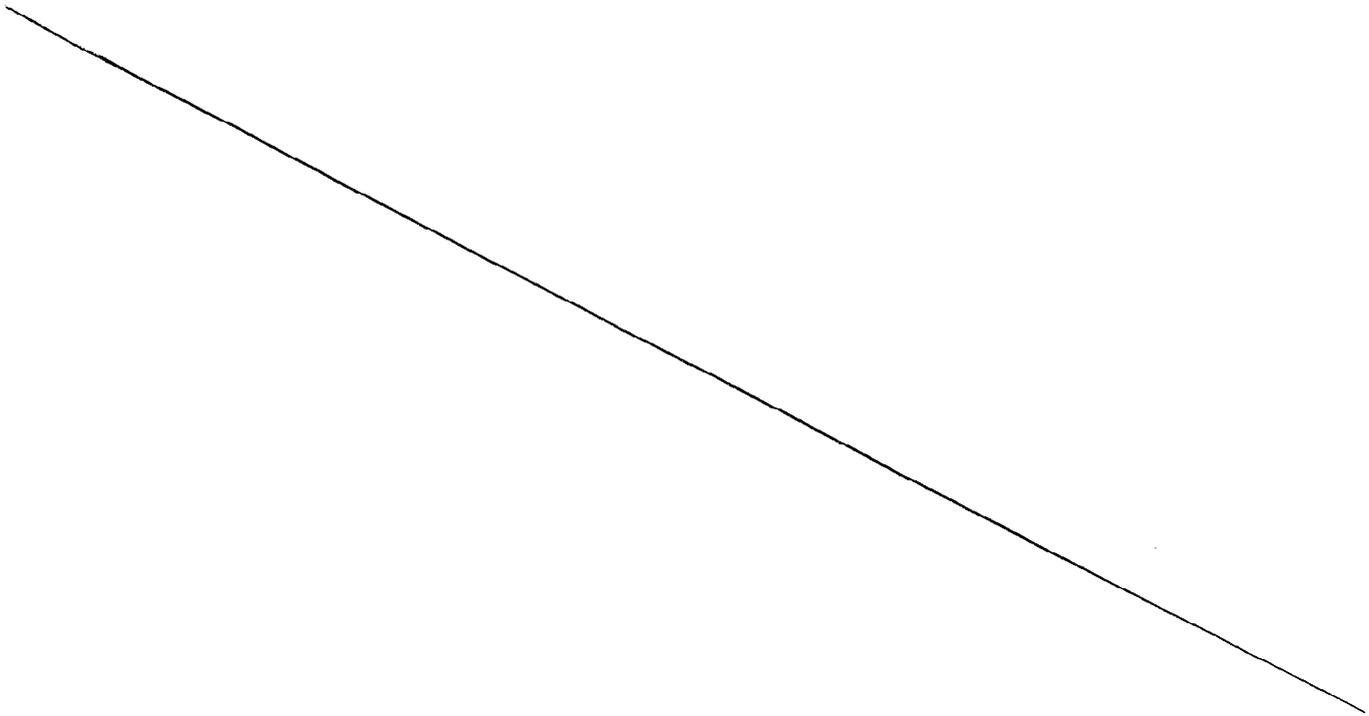
agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

## **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

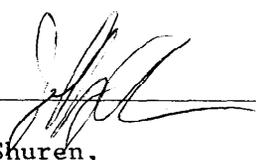
## **III. Electronic Access**

Persons with access to the Internet may obtain the guidance 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



<http://www.aabb.org>. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Dated: 12/1/03  
December 1, 2003.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

COPIES ORIGINAL

