

DMB

Display Date	6-5-00
Expiration Date	6-6-00
Certifier	SVR/ase

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0965]

“Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of 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 guidance document entitled “Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components.” The guidance document describes a system for the uniform labeling of blood and blood components for transfusion, Source Plasma, and other components for use in further manufacturing. The guidance will assist manufacturers in complying with the labeling requirements under FDA’s regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled “Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components” to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 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 document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

NAD 2

Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information about this notice: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

For technical information: Kenneth A. Zemann, Center for Biologics Evaluation and Research (HFM-375), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3543, or FAX 301-827-3534.

SUPPLEMENTARY INFORMATION:

I. Background

The International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA a draft document entitled "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*," Version 1.2.0 (draft Standard). The ICCBBA requested that ISBT 128 replace the current "ABC Codabar" system as an approved machine readable barcode for labeling blood and blood components. On November 21, 1998, FDA made the draft Standard available on its website for public comment. In the **Federal Register** of November 27, 1998 (63 FR 65600), FDA announced the availability of the draft Standard and requested public comment on both the use of ISBT 128 and timeframes for implementation. The ICCBBA revised the draft Standard in response to public comment and submitted to FDA the revised document entitled "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*," Version 1.2.0, dated November 1999 (the Version 1.2.0 Standard).

FDA has reviewed the draft Standard, the comments received, and the Version 1.2.0 Standard. FDA believes that conformance to the Version 1.2.0 Standard, prepared and revised by ICCBBA, will help facilitate the use of a uniform container label for blood and blood components. FDA

is announcing the availability of a guidance entitled "Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components" that recognizes as acceptable the Version 1.2.0 Standard prepared by ICCBBA, and the implementation of the ISBT 128 uniform labeling system, except where inconsistent with FDA's regulations under 21 CFR 606.121. Although FDA finds use of the Version 1.2.0 Standard acceptable, FDA has identified inconsistencies between the Version 1.2.0 Standard and Federal regulations. FDA intends to revise the regulations to remove these inconsistencies. The guidance provides recommendations to follow where discrepancies exist between the Version 1.2.0 Standard and the current regulations, pending completion of rulemaking to remove these discrepancies.

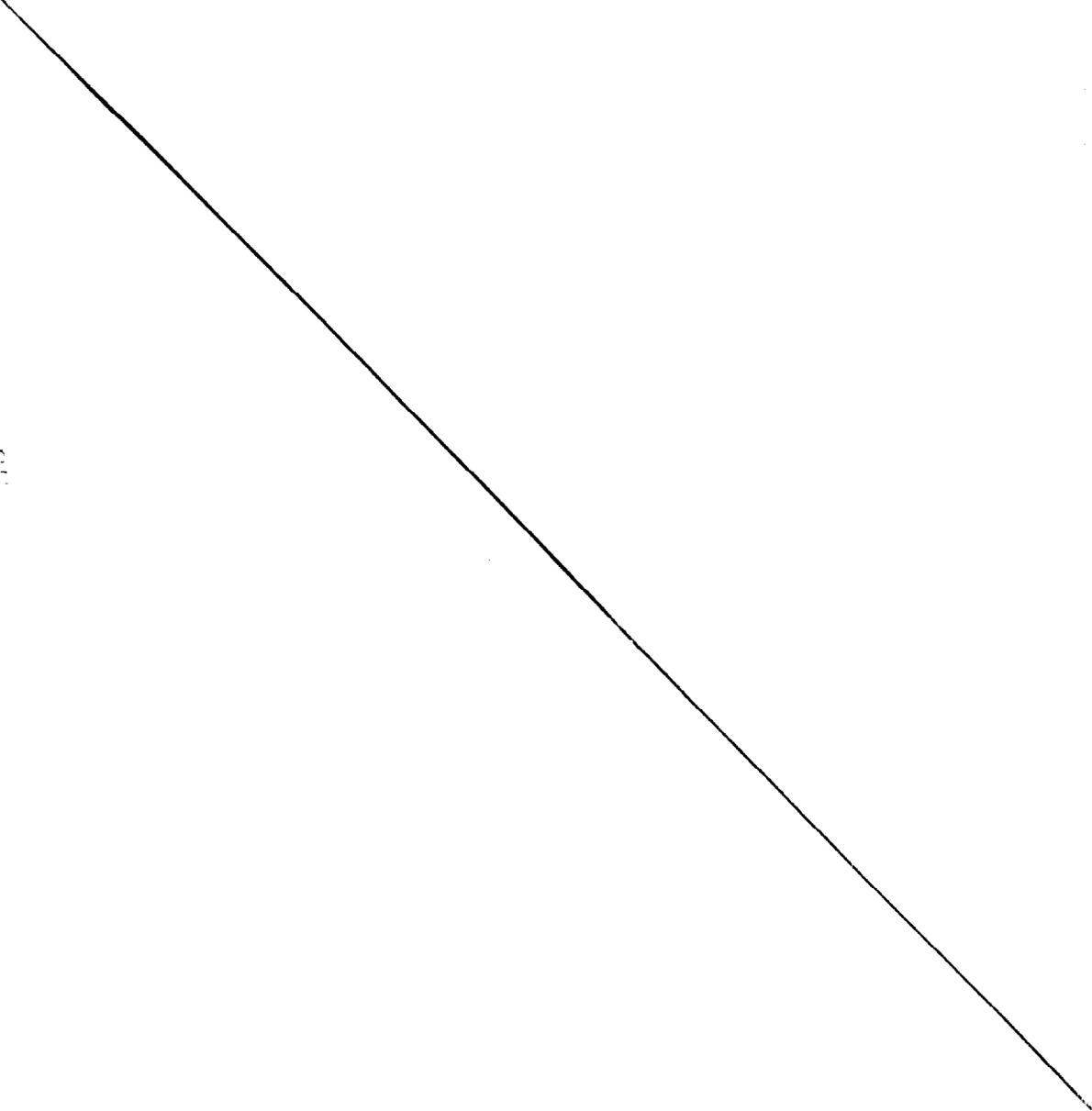
This guidance document represents the agency's current thinking with regard to use of the Version 1.2.0 Standard for use in labeling blood, blood components for transfusion, Source Plasma, and other components for further manufacturing use. It does not create or confer any rights for or on any person 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document at any time. 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 the 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. Paperwork Reduction Act of 1995

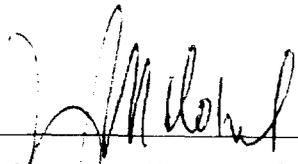
The labeling regulations on which the guidance is based are reported under the Office of Management and Budget (OMB) control number 0910-0116. FDA tentatively concludes that this guidance contains no new collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.



IV. Electronic Access

Persons with access to the Internet may obtain the guidance document and the Version 1.2.0 Standard at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 5/25/00
May 25, 2000

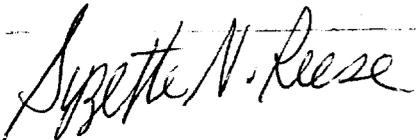


Margaret M. Dotzel
Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

~~ESTIMATED TO BE A TRUE COPY OF THE ORIGINAL.~~



Suzanne N. Reese