

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0037]

DMB

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Certifier	<u>SREESE</u>

Draft "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion;" 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: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion." The draft guidance document provides recommendations on manufacturing and quality assurance applicable to pre-storage leukocyte reduction of blood components intended for transfusion. This draft guidance document describes manufacturing procedures and controls that should be in place and would supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by [*insert date 90 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final guidance document.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" 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, suite 200N, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion." The draft guidance document provides FDA recommendations regarding leukocyte reduction and provides information to assist licensed facilities in filing supplements to their biologics licenses to include leukocyte reduced products.

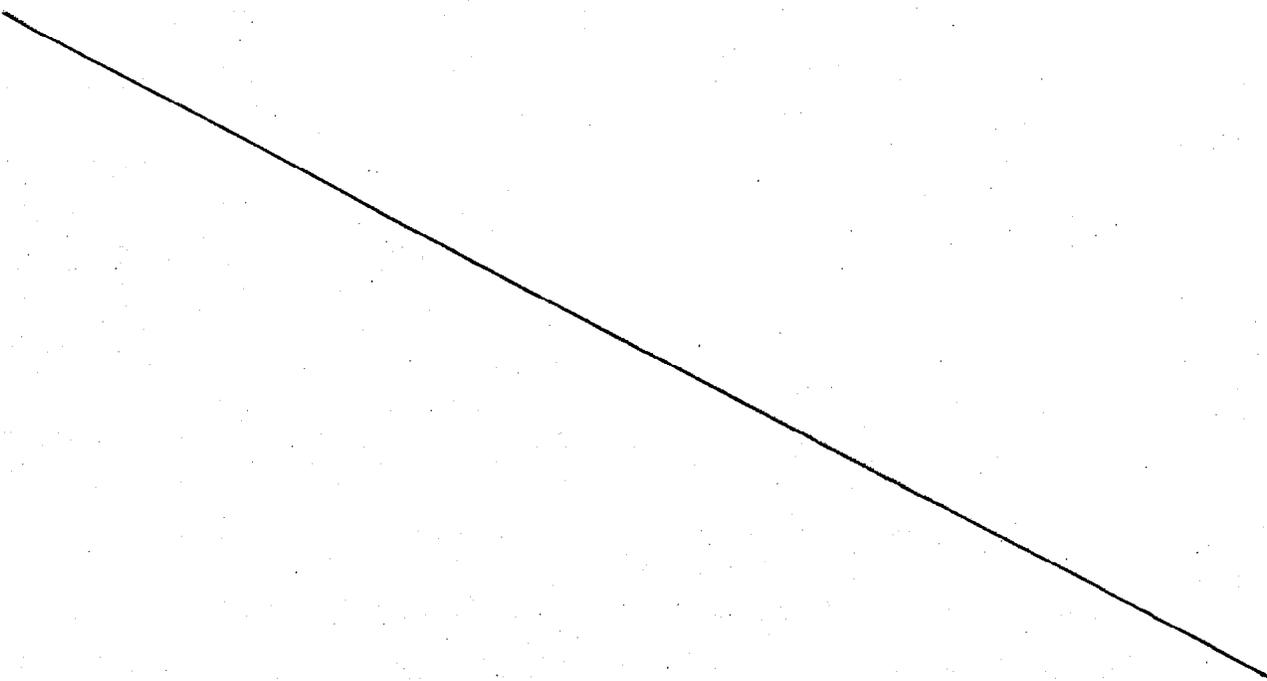
This draft guidance document describes the manufacturing procedures and controls applicable to pre-storage leukocyte reduced blood components for transfusion. Additionally, the agency would streamline the licensing procedure for leukocyte reduced products in order to assist blood establishments in making pre-storage leukocyte reduced products more widely available.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the leukocyte reduction of blood components intended for transfusion. 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 and regulations. 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

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 (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by [*insert date 90 days after date of publication in the Federal Register*], 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 at <http://www.fda.gov/cder/guidance/index.htm> or at <http://www.fda.gov/cber/guidelines.htm>.

Dated: January 22, 2001
January 22, 2001

Ann M. Witt

Ann M. Witt
Acting Associate Commissioner for Policy

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