

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5046]

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“Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture;” 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: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” dated July 2001. The guidance document provides information about reporting changes to licensed biological products including labeling, production processes, quality controls, equipment, and facilities that have been documented in approved license applications. The guidance document is intended to assist biological product manufacturers in identifying the kinds of changes to be reported, the category into which the change is to be placed, and the time to report the change to FDA.

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

ADDRESSES: Submit written requests for single copies of this 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 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.

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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, 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: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” dated July 2001. CBER developed the guidance in response to public comments on the “Guidance for Industry: Changes to an Approved Application: Biological Products” dated July 1997 and public comments on the CBER Biologics Workshop on the Biologics License Application (BLA), December 2, 1997. The guidance applies to the manufacture of all licensed Whole Blood, blood components, Source Plasma, and Source Leukocytes. The guidance is intended to assist biological product manufacturers in identifying the kinds of changes to be reported, the category into which the change is to be placed, and the time to report the change to FDA.

This guidance replaces the recommendations for the products mentioned above in the “Guidance for Industry: Changes to an Approved Application: Biological Products” dated July 1997 and revises and finalizes the draft guidance entitled “Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” dated January 2000 that was announced in the **Federal Register** of January 3, 2000 (65 FR 134).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on reporting changes to an approved application for human blood and blood components that are intended for transfusion or for further manufacture. 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

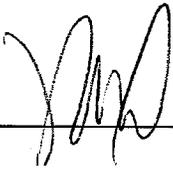
Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in 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.

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III. Electronic Access

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

Dated: 6/29/01
June 29, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



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