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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5046]

Draft "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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture." The draft guidance document applies to the manufacture of all licensed Whole Blood, blood components, Source Plasma, and Source Leukocytes. The draft guidance document, when finalized, is intended to assist manufacturers in determining which reporting mechanism is appropriate for a change to an approved license application for Whole Blood, blood components, Source Plasma, and Source Leukocytes.

DATES: Submit written comments 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 document.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture" 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-

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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 1-806835-4709 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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. 106 1, Rockville, MD 20852.

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 guidance document entitled "Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture." The draft guidance document is intended to assist licensed manufacturers in determining which reporting mechanism is appropriate for a change to an approved license application for Whole Blood, blood components, Source Plasma, and Source Leukocytes. Recommendations are provided for postapproval changes in product, labeling, production process, quality controls, equipment, and facilities.

In the **Federal Register** of July 24, 1997 (62 FR 39890), FDA published the final rule entitled 'Changes to an Approved Application.' The final rule amended the **biologics** regulations in § 601.12 (21 CFR 601.12) to reduce unnecessary reporting burdens on applicants licensed to manufacture biological products under the Public Health Service Act. Under § 601.12, a change to an approved product, labeling, production process, quality controls, equipment, or facilities is required to be reported to FDA in the following manner: (1) A supplement requiring approval prior to distribution; (2) a supplement submitted at least 30 days prior to distribution of the product

made using the change; or (3) an annual report, depending on its potential to have an adverse effect on the identity, strength, quality, purity, or potency of the biological product as they may relate to the safety or effectiveness of the product. In addition, FDA made available a guidance document entitled “Guidance for Industry: Changes to an Approved Application: Biological Products” published in the **Federal Register** of July 24, 1997 (62 FR 39904).

On December 2, 1997 (62 FR 56193, October 29, 1997), CBER held a public workshop entitled “Workshop on the **Biologics** License Application (BLA) for Blood Products, and Reporting Changes to an Approved Application.” The workshop was intended for firms that manufacture licensed human blood products, including products for transfusion and source materials for further manufacture. The workshop discussion focused on the application procedures, forms, and documentation needed for the BLA and how changes to an approved application are to be reported to FDA.

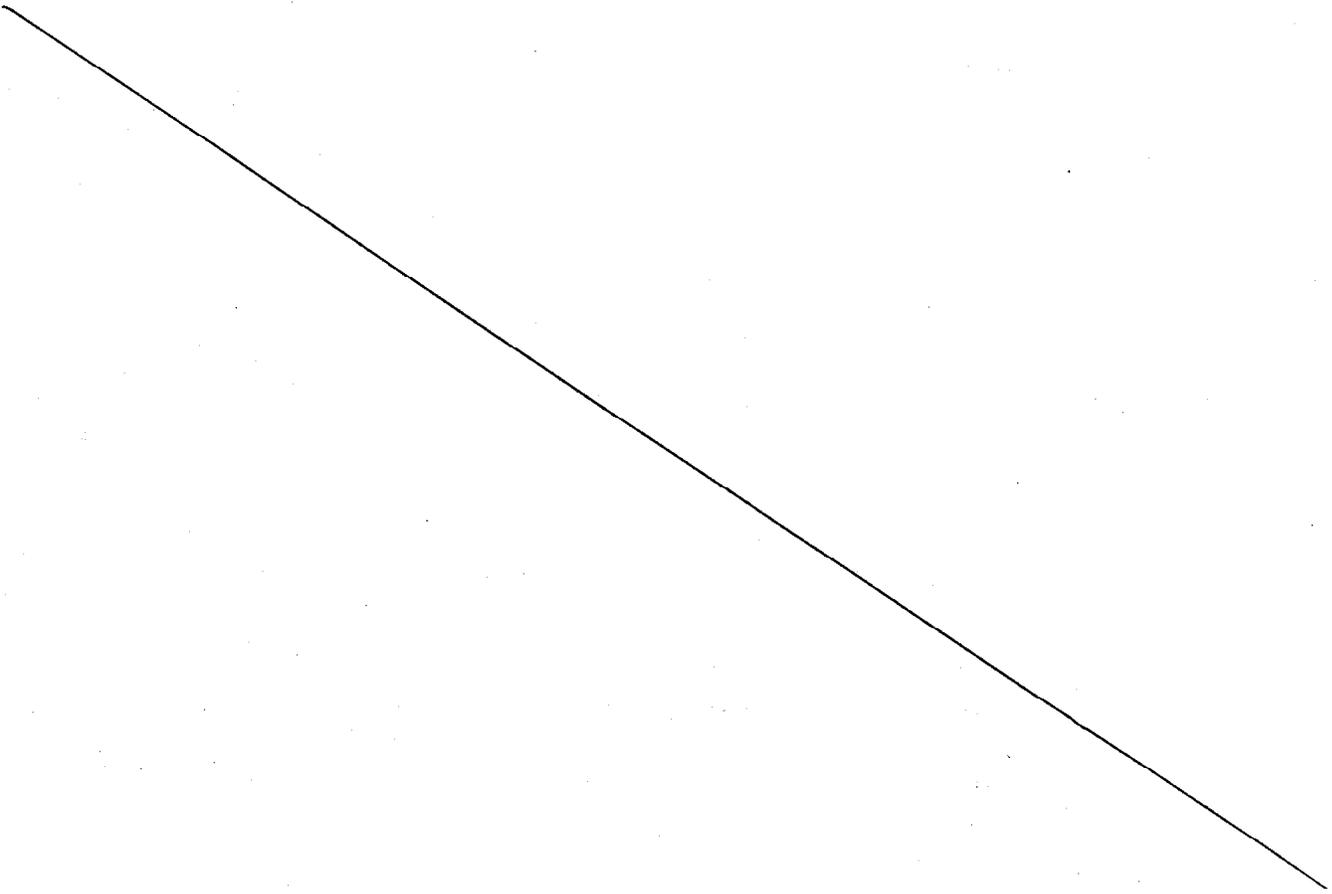
In response to comments received from industry requesting guidance specifically for blood and blood components, CBER has developed the draft guidance document for the manufacturers of licensed Whole blood and blood components intended for transfusion and for further manufacture into both injectable and noninjectable products. The draft guidance document, when finalized, will replace the recommendations in the “Guidance for Industry: Changes to an Approved Application: Biological Products” for Whole Blood, blood components, Source Plasma, and Source Leukocytes. The “Guidance for Industry: Changes to an Approved Application: Biological Products” remains applicable for all other biological products.

This draft guidance document represents the agency’s current thinking on changes to an approved application for all licensed human blood and blood components 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 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

This draft guidance 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. Submit written comments 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 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.

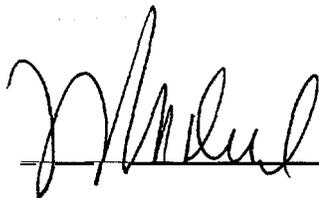


III. Electronic Access

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

Dated: 12/22/99

December 22, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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