DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 1999-D-3528 (formerly Docket No. 1999D-5046)]

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry" dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved biologics license application (BLA). The guidance document also provides manufacturers of licensed whole blood and blood components recommendations in connection with the applicability and content of comparability protocols and labeling changes. The guidance applies to the manufacture and distribution of licensed products. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the document of the same title dated July 2001 (July 2001 guidance).

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research

(CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry" dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved BLA in accordance with the requirements under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12). The guidance document also provides manufacturers of licensed whole blood and blood components with recommendations in connection with the applicability and content of comparability protocols under § 601.12(e) and labeling changes under § 601.12(f). Frequently, a manufacturer

of a licensed product determines that it is appropriate to make a change in its product, production process, quality controls, equipment, facilities, responsible personnel, or labeling as documented in its approved BLA(s). Section 601.12 states the requirements to report such changes for licensed biological products to FDA.

The recommendations contained in the guidance document reflect current FDA and industry experience with reporting changes to an approved application, including reporting the implementation of new technologies. The recommendations have been revised for reporting categories for certain changes to an approved application that were in the July 2001 guidance based on the experience gained over the last decade.

In the Federal Register of May 31, 2013 (78 FR 32668), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments, the guidance includes the addition of numerous appendices with tables to highlight the appropriate reporting categories related to certain manufacturing changes. The guidance announced in this notice finalizes the draft guidance dated June 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 601.12 and Form FDA 356h have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 607.26 and Form FDA 2830 have been approved under OMB control number 0910-0052; the collections of information in 21 CFR 606.121, 606.170, and 610.40 have been approved under OMB control number 0910-0116; and the collections of information in 21 CFR 600.14 have been approved under OMB control number 0910-0458.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-27521 Filed 11/20/2014 at 8:45 am; Publication Date: 11/21/2014]