4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-3528 (formerly 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Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture;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 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 June 2013. The draft guidance document provides manufacturers of licensed Whole Blood and blood components intended for transfusion or for further manufacture, including Source Plasma, with recommendations intended to assist with determining which reporting mechanism is appropriate for submission of changes to an approved biologics license application. 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 The draft guidance, when finalized, is intended to supersede the document of the same title dated July 2001 (July 2001 guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 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 June 2013. The document provides manufacturers of licensed Whole Blood and blood components intended for transfusion or for further manufacture, including Source Plasma, with recommendations intended to assist with determining which reporting mechanism is appropriate for submission of changes to an approved biologics license application in accordance with the requirements under Title 21 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 21 CFR 601.12(e) and labeling changes under 21 CFR 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 biologics license application(s). Section 601.12 (21 CFR 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 is in the July 2001 guidance based on the experience gained over the last decade. The draft guidance, when finalized, is intended to supersede the document of the same title dated July 2001, published in the FEDERAL REGISTER of August 7, 2001 (66 FR 41247).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft 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, Form FDA 2567, and Form FDA 356h have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 607.21, 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 has been approved under OMB control number 0910-0458.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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