4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0187 (formerly Docket No. 2000D-1267)]

Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; 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: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria" dated August 2013. The guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, allowing their reentry, and product management to reduce the risk of transfusion-transmitted malaria. This guidance finalizes the draft guidance of the same title dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled “Recommendations for Deferral of Donors for Malaria Risk” dated July 26, 1994. The recommendations contained in the guidance are not applicable to donors of Source Plasma.

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 (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 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 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: Melissa Reisman, 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 guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria" dated August 2013. The guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, and allowing their reentry, to reduce the risk of transfusion-transmitted malaria. This guidance document also provides recommendations for product management, including recommendations regarding product retrieval and quarantine, and notification of consignees of blood and blood components in the event that a blood establishment determines that blood or blood components have been collected from a donor who should have been deferred due to possible malaria risk. Finally, the guidance contains recommendations on the implementation of FDA's

recommendations, including how licensed blood establishments must report to FDA the changes made to their donor history questionnaires to reflect the new donor deferral recommendations.

In the Federal Register of July 6, 2012 (77 FR 40068), FDA announced the availability of the draft guidance of the same title dated June 2012. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Significant changes to the guidance include: revisions to the definition of malaria-endemic area, malaria-endemic country and other terms used to assess a donor's risk of malaria based on history of travel or residence; and revisions to the recommendations regarding consignee notification and reporting of biological product deviations for acellular blood components collected from a donor at risk for malaria. Based on the revised definition of malaria-endemic area and current epidemiological data, donors who travel to the Mexican States of Quintana Roo or Jalisco would be eligible for donation without any deferral, provided the donors meet all other eligibility criteria. However, if malaria transmission in these States changes over time, the donor deferral recommendations would encompass donors who travel to these areas. The guidance announced in this notice finalizes the draft guidance dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled "Recommendations for Deferral of Donors for Malaria Risk," dated July 26, 1994.

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

This 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 part 640 and 21 CFR 630.6 have been approved under OMB control number 0910-0116. The collections of information in 21 CFR 606.171 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: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-19962 Filed 08/16/2013 at 8:45 am; Publication Date: 08/19/2013]