4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria" dated June 2012. The draft guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood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 This guidance replaces the draft guidance entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated June 2000. The draft guidance, when finalized, will supersede the FDA memorandum to all registered blood establishments entitled "Recommendations for Deferral of Donors for Malaria Risk"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 The recommendations contained in the draft guidance are not applicable to donors of Source Plasma.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 60 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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 guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management

to Reduce the Risk of Transfusion-Transmitted Malaria" dated June 2012. The draft 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 draft 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 draft guidance revises FDA's policy regarding donors who are residents of non-endemic countries and who have traveled to the Mexican states of Quintana Roo or Jalisco, and allows for donation without any deferral for malaria risk, provided the donor meets all other donor eligibility criteria.

The draft guidance replaces the draft guidance entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated June, 2000, and, when finalized, will supersede the FDA memorandum to all registered blood establishments entitled "Recommendations for Deferral of Donors for Malaria Risk," dated July 26, 1994. Since publication of these documents, FDA convened a scientific workshop on "Testing for Malarial Infections in Blood Donors" in July 2006, and also discussed the issue of blood donor deferral for malaria risk with the FDA Blood Products Advisory Committee (BPAC) on several occasions. The recommendations contained in the draft guidance are based, in part, on recommendations from BPAC, the public comments received on the earlier documents, and the comments received during the scientific workshop. In addition, FDA is aware that dengue viruses are endemic in Quintana Roo and Jalisco. FDA is currently evaluating

the risk of dengue virus infections in U.S. blood donors that are acquired either locally or elsewhere in the world, including in Mexico, and may address this issue in future guidance.

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

This 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 part 640 have been approved under OMB control number 0910-0116. The collections of information in 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

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

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: June 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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