4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2003-D-0128 (Legacy ID: FDA-2003D-0236)]

Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis; 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 Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis," dated September 2014. The guidance document provides recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The guidance is intended for blood establishments that collect Whole Blood or blood components, including Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title, dated March 2013 (2013 draft guidance), and supersedes the memorandum of December 12, 1991, entitled "Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing."

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: Paul E. Levine, Jr., Center for Biologics Evaluation and Research, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G112, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled, "Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis," dated September 2014. The guidance document provides recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The recommendations described in the document are for blood establishments that use either nontreponemal or treponemal screening assays to test donors for serological evidence of syphilis infection.

In the Federal Register of February 26, 2013 (78 FR 13069), FDA announced the availability of the 2013 draft guidance. FDA received several comments on the 2013 draft guidance and those comments were considered as the guidance was finalized. In summary, FDA modified the recommendations provided in the 2013 draft guidance concerning the use of an FDA-cleared nontreponemal donor screening assay to test donations from reentered donors. In

addition, FDA made editorial changes to recommendations in the guidance to improve clarity. The guidance announced in this notice finalizes the 2013 draft guidance.

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 requirement 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 601.12 have been approved under OMB control number 0910-0338; and 21 CFR 606.121, 606.160, 610.40, 630.6, 640.3, 640.65, and 640.71 have been approved under OMB control number 0910-0116.

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 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-20483 Filed 08/27/2014 at 8:45 am; Publication Date: 08/28/2014]