4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2003-D-0128] (formerly 2003D-0236)

Draft Guidance for Industry: Recommendations for Screening, Testing, and, Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis;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 draft 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 March 2013. The draft guidance document provides revised recommendations for screening and testing of donors and management of donations based on screening tests for syphilis. The draft guidance is intended for blood establishments that collect Whole Blood or blood components, including Source Plasma. The guidance announced in this notice replaces the draft guidance entitled, "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis," dated June 2003. In addition, the draft guidance, when finalized, is intended to supersede the FDA memorandum to registered blood establishments dated December 12, 1991, entitled, "Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing."

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis," dated March 2013. The draft guidance document provides revised 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 non-treponemal or treponemal screening assays to test donors for serological evidence of syphilis infection.

In the Federal Register of June 26, 2003 (68 FR 38083), FDA announced the availability of the draft guidance entitled, "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis," dated June 2003. The draft guidance announced in this notice replaces the 2003 draft guidance and when finalized, is intended to supersede the FDA memorandum to all registered blood establishments dated December 12, 1991, entitled, "Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing."

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 630.6 and 606.160 have been approved under OMB control number 0910-0116.

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: February 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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