4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1213]

Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection With Treponema pallidum (Syphilis); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with Treponema pallidum (Syphilis); Guidance for Industry." The guidance document provides establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/P Establishments) with updated recommendations concerning donor testing for evidence of Treponema pallidum (T. pallidum) infection, the etiologic agent of syphilis. HCT/P Establishments must, as required under Federal regulations, test a donor specimen for evidence of T. pallidum infection using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies. The guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor

testing for T. pallidum infection under the criteria specified in Federal regulations. The guidance announced in this notice finalizes the draft guidance of the same title, dated October 2013. The recommendations in the guidance announced in this notice supersedes those recommendations for testing HCT/P donors for evidence of T. pallidum infection contained in the document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated August 2007.

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 240-402-8010. 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, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with Treponema pallidum (Syphilis); Guidance for Industry." The guidance document provides HCT/P Establishments with updated recommendations concerning donor testing for evidence of T. pallidum infection. HCT/P Establishments must, as required under § 1271.80(a) and (c) (21 CFR 1271.80(a) and (c)), test a donor specimen for evidence of infection due to T. pallidum using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies under 21 CFR 1271.90. The guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for T. pallidum infection under the criteria specified in § 1271.80(c). FDA will no longer exercise enforcement discretion that permits the use of diagnostic syphilis tests or pre-amendments devices for use as an HCT/P donor screening test because the wide availability of FDA-licensed, approved, or cleared test systems with an indication for use in donor screening no longer supports such enforcement discretion. FDA recommends that HCT/P Establishments implement the recommendations in the guidance as soon as feasible, but not later than 6 months after issuance of this guidance.

In the Federal Register of November 5, 2013 (78 FR 66366), FDA announced the availability of the draft guidance of the same title, dated October 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. FDA did not make changes to the recommendations in the draft guidance. FDA made

editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2013.

In the Federal Register of February 28, 2007 (72 FR 9007), FDA announced the availability of the guidance entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated February 2007. FDA issued a revised version of this guidance under the same title, dated August 2007 (hereafter referred to as the 2007 Donor Eligibility guidance). The guidance announced in this notice supersedes the recommendations on compliance with the requirements for testing HCT/P donors for T. pallidum that are contained in the 2007 Donor Eligibility guidance.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with Treponema pallidum (Syphilis); Guidance for Industry." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. 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.

III. 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: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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