4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection with Treponema pallidum (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: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with Treponema pallidum (Syphilis)," dated October 2013. The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps (HCT/P Establishments), with updated recommendations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 The draft guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in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 recommendations in this guidance, when finalized, will supersede 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: 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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: Paul E. Levine, Jr., 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 draft document entitled "Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with Treponema pallidum (Syphilis)," dated October 2013. The draft 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 draft 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.

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 draft guidance

announced in this notice, when finalized, will supersede the recommendations for testing HCT/P donors for T. pallidum that were contained in the 2007 Donor Eligibility 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. 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.

III. 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: October 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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