

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In the **Federal Register** of November 5, 2013 (78 FR 66366), FDA announced the availability of the draft guidance of the same title, dated October 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. FDA did not make changes to the recommendations in the draft guidance.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 The guidance announced in this notice finalizes the draft guidance dated October 2013.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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–N–0001]

#### Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop; Public Workshop; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 3, 2015 (80 FR 45998). That notice, announcing the

sixth annual scientific workshop co-sponsored by FDA and the Coalition Against Major Diseases Consortium of the Critical Path Institute, contained incorrect Web links for online registration and for the FDA Meeting Information Page (where the workshop agenda will be made available) and an incorrect registration deadline. This document corrects those errors.

#### FOR FURTHER INFORMATION CONTACT:

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**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015–18969, appearing on page 45998, in the **Federal Register** of Monday August 3, 2015, the following corrections are made:

On page 45998, in the second full paragraph of the third column, the registration link, <https://www.SignUp4.net/public/ap.aspx?EID=SIXT10E>, is corrected to read <http://www.cvent.com/events/6th-annual-coalition-against-major-diseases-food-and-drug-administration-scientific-workshop-public/invitation-ed6c207cbf09447185a891e4bf62ad7a.aspx?i=70715ca1-f255-46b2-a370-3fe3881bbab2>.

On page 45998, in the third full paragraph of the third column, the registration deadline, October 14, 2015, is corrected to read October 13, 2015.

On page 45998, in the third full paragraph of the third column, the link for the FDA Meeting information page, <http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm>, is corrected to read <http://www.fda.gov/Drugs/NewsEvents/ucm457486.htm>.

Dated: September 2, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–N–3015]

#### Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.