DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0137]

Amendment to Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry.'' The draft guidance document, when finalized, is intended to amend the document entitled ''Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion'' dated December 2010 (2010 Chagas Guidance) by expanding the scope of the guidance to include the collection of blood and blood components for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device; removing the recommendation to ask donors about a history of Chagas disease; and providing a recommendation for a reentry algorithm for donors deferred on the basis of screening test results for antibodies to *Trypanosoma cruzi* (*T. cruzi*) or on the basis of answering ''yes'' to the Chagas screening question. Further, the guidance is intended to notify blood establishments that collect blood and blood components that FDA has licensed a supplemental test for antibodies to *T. cruzi* and further testing of donations found repeatedly reactive to a screening test for *T. cruzi* is therefore required. The draft guidance does not apply to the collection of Source Plasma.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 8, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–D–0137 for ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 draft document entitled ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry.'' The draft guidance, when finalized, is intended to amend the 2010 Chagas Guidance (75 FR 75810, December 6, 2010) by expanding the scope of the guidance to include the collection of blood and blood components for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device; removing the recommendation to ask donors about a history of Chagas disease; and providing a recommendation for a reentry algorithm for donors deferred on the basis of screening test results for antibodies to *T. cruzi* or on the basis of answering ''yes'' to the Chagas screening question.

In the **Federal Register** of May 22, 2015 (80 FR 29842), FDA published the final rule entitled ''Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use.'' The final rule became effective May 23, 2016. The draft guidance is intended to notify blood establishments that collect blood and blood components that *T. cruzi* is defined as a relevant transfusion-transmitted infection in 21 CFR 630.3(h)(1), subject to the testing requirements in 21 CFR 610.40, the donor deferral practices in 21 CFR 610.41, and the donor notification requirements in 21 CFR 630.40 under the final rule. In addition, the draft guidance is intended to notify blood establishments that collect blood and blood components that FDA has licensed a supplemental test for antibodies to *T. cruzi* and further testing of donations found repeatedly reactive to a screening test for *T. cruzi* is therefore required under 21 CFR 610.40(e). The draft guidance does not apply to the collection of Source Plasma. All other recommendations in the 2010 Chagas Guidance would remain unchanged.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion; Draft 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. 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 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 610.40 and 630.40 have been approved under OMB control numbers 0910–0116 and 0910–0795.

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: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27107 Filed 11–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings are open to the public.

Name of Committee: Health IT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the Health IT Policy Committee.

2016 Meeting Dates and Times

- December 6, 2016 from 9:30 a.m. to 1:30 p.m./Eastern Time (replacing the formerly announced November 2 and December 7 meetings)
  - This will be a virtual Joint Health IT Policy and Health IT Standards Committee meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, *http://www.healthit.gov/FACAS/calendar.*

Contact Person: Michelle Consolazio, email: *michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for the most current information about meetings. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups/task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://www.healthit.gov/facas/health-it-standards-committee.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with