DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0137]

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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA approvals of biologics license applications for serological test systems for the detection of antibodies to *Trypanosoma cruzi*. These tests are intended for use as donor screening tests to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance announced in this document finalizes the draft guidance entitled "Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated March 2009. The recommendations for HCT/P donor screening and testing for *T. cruzi* antibodies contained in the draft guidance are not being finalized at this time because FDA believes additional discussion is warranted. Elsewhere in this issue of the **Federal Register,** FDA is publishing a 30-day notice announcing that the proposed collection of information for the guidance has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

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 (HFM–40), Center for Biologics Evaluation and Research, 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 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 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: Valerie A. Butler, 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 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. The guidance document notifies establishments that manufacture whole blood and blood components intended for transfusion about FDA license approvals for serological test systems for the detection of antibodies to *T. cruzi.* These tests are intended for use as donor screening tests to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors. The guidance document provides recommendations for one time testing of donations of whole blood and blood components for evidence of *T. cruzi* infection, blood donor and product management, labeling of whole blood and blood components, and procedures for reporting the implementation of a licensed *T. cruzi* test. The guidance document does not apply to the collection of source plasma. Also, the guidance does not apply to establishments that make eligibility determinations for donors of HCT/Ps. The recommendations for HCT/P donor screening and testing for *T. cruzi* antibodies contained in the draft guidance are not being finalized at this time because FDA believes additional consideration of the recommendations is warranted.

At the April 2009 Blood Products Advisory Committee (committee) meeting, FDA sought advice from the committee regarding selective testing strategies for *T. cruzi* infection in repeat blood donors. After discussing the testing strategies presented, the committee voted in favor of a selective testing strategy in which one negative test would qualify a donor for all future donations without further testing or the need to ask questions regarding risk of a newly acquired *T. cruzi* infection.

In the **Federal Register** of March 26, 2009 (74 FR 13211), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated March 2009. The guidance announced in this document finalizes only the recommendations concerning testing donations of whole blood and blood components intended for transfusion for *T. cruzi* antibodies.

At this time, FDA is continuing to review public comments on our recommendations for testing HCT/P donors for *T. cruzi.* Therefore, we are not finalizing our recommendations for HCT/Ps in this guidance. We intend to issue guidance for testing HCT/P donors for *T. cruzi* infection in the future.

FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes also were made to improve clarity.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Elsewhere in this issue of the **Federal Register**, FDA is publishing a 30-day notice entitled "Agency Information Collection

Activities; Submission for Office of Management and Budget Review; Comment Request; 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," which announces that the proposed collection of information has been submitted to OMB for review and clearance under the Paperwork Reduction Act. FDA will publish a notice concerning OMB approval of these information collection provisions in the **Federal Register** prior to the implementation date provided in the guidance document.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written or comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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: November 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0137]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of 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.

DATES: Fax written comments on the collection of information by January 5, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title "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." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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—(OMB Control Number 0910–NEW)

The guidance document, announced elsewhere in this issue of the **Federal Register**, would implement the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to *Trypanosoma cruzi.* The use of the donor screening tests are to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of whole blood and blood components intended for transfusion. The guidance recommends that establishments that manufacture whole blood and blood components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to the establishments or to destroy them within 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for *T. cruzi* antibodies and for whom there is additional information indicating risk of *T. cruzi* infection, such as testing positive on a licensed supplemental test (when such test is available) or until such test is available, information that the donor or donor's mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or as a result of other medical diagnostic testing of the donor indicating *T. cruzi* infection, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the lookback period and, if blood or blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Respondents to this information collection are establishments that manufacture whole blood and blood components intended for transfusion. We believe that the information collection provisions for consignee notification and for consignees to notify the recipient's physician of record in the guidance do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood