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.

[FR Doc. 2010–30405 Filed 12–3–10; 8:45 am]

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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

centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and the consignees to notify the recipient's physician of record.

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.

In the **Federal Register** of March 26, 2009 (74 FR 13211), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

Dated: November 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30404 Filed 12–3–10; 8:45 am]

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