



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0137]

Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; 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 document entitled "Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry." The guidance document provides recommendations to blood collection establishments regarding the use of serological tests to reduce the risk of transmission of *Trypanosoma cruzi* (*T. cruzi*) infection in blood and blood components. The recommendations apply to the collection of blood and blood components, except Source Plasma, for transfusion or for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device. The guidance announced in this notice supersedes the 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Whole Blood and Blood Components Intended for Transfusion" dated December 2010 (2010 Chagas Guidance) and finalizes the draft guidance entitled "Amendment to 'Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion'; Draft Guidance for Industry" dated November 2016 (2016 Draft Chagas Guidance). The

guidance incorporates recommendations for blood donor testing, deferral, and donor reentry from the 2016 Draft Chagas Guidance.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 "Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the 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 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 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 document entitled "Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry." The guidance document addresses the use of serological tests to reduce the risk of transmission of *T. cruzi* infection in blood and blood components. The recommendations apply to the collection of blood and blood components, except Source Plasma, for transfusion or for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device. The guidance incorporates recommendations for blood donor testing, deferral, notification, and donor reentry from the 2016 Draft Chagas Guidance. The 2016 Draft Chagas Guidance amended the 2010 Chagas Guidance by (1) 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; (2) removing the recommendation to ask donors about a history of Chagas disease; and (3) providing a recommendation for a reentry algorithm for certain 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. The 2016 Draft Chagas Guidance also provided notice that FDA had 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).

In the *Federal Register* of December 6, 2010 (75 FR 75810), FDA announced the availability of the 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 Intended for Transfusion" dated December 2010. In the *Federal Register* of

November, 10, 2016 (81 FR 79034), FDA announced the availability of the draft guidance 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" dated November 2016. FDA received two comments on the 2016 Draft Chagas Guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice supersedes the 2010 Chagas Guidance and finalizes the 2016 Draft Chagas Guidance.

This 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 Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components." 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The guidance refers to the following collections of information: (1) establishments notify consignees of all previously collected in-date blood and blood components from a donor that tests repeatedly reactive by a licensed test for *T. cruzi* antibody to quarantine and return the blood and blood components to the establishments or to destroy them; (2) establishments notify consignees of all previously distributed blood and blood components collected from such a donor during the lookback period; and (3) if such blood components were transfused, consignees notify the recipient's physician of record of a possible increased risk of *T.*

cruzi infection. These collections of information have been approved under OMB control number 0910-0681.

This guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; and the collections of information in 21 CFR parts 606, 610, and 630 have been approved under OMB control numbers 0910-0116 and 0910-0795.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 30, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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