FOOD AND DRUG ADMINISTRATION
Guidance for Industry (GFI): Use of Serological Tests to
Reduce the Risk of Transmission of *Trypanosoma cruzi* (*T. cruzi*) Infection in
Whole Blood and Blood Components Intended for Transfusion

OMB Control No. 0910-0681

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) guidance entitled, "*Guidance for Industry (GFI): Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion*." The guidance establishes donor screening recommendations for the FDA approved serological test systems for the detection of antibodies to *T. cruzi*. The purpose of the donor screening tests is 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 and blood components to 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* and positive on a licensed supplemental test, FDA recommends 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, to encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Thus, the information collection provisions found in the guidance include recommendations that establishments notify consignees of all previously distributed blood and blood components that tested repeatedly reactive for the *Trypanosoma cruzi* (*T. Cruzi*) antibody; and recommendations that consignees to notify the recipient's physician of record of a possible increased risk of *Trypanosoma cruzi* infection, if the recipient was transfused with a blood or blood components from a donor who tested repeatedly reactive for *Trypanosoma cruzi* antibody.

Accordingly, we are requesting OMB approval for the information collection provisions found in the agency guidance entitled, ""*Guidance for Industry (GFI): Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion*."

2. Purpose and Use of the Information Collection

The notification of consignees and of the recipient's physician of record is intended to provide the necessary information regarding possible increased risk of *T. cruzi* infection. All donors who test repeatedly reactive should be counseled to seek a physician's advice. It also may be helpful to refer them to their state and local health departments or to other appropriate community resources.

3. Use of Improved Information Technology and Burden Reduction

Notification of consignees or the recipient's physician of record can be accomplished by email, phone, fax, or mail. FDA is not aware of any improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection applies to all respondents without exemption. At the same time, the agency provides industry assistance through agency guidance and by contacting agency personnel. Information in this regard may be found on the agency's website at: www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with recommendations found in agency guidance. We believe this presents minimal burden on respondents while ensuring the safety of the nation's blood supply.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of November 7, 2016 (81 FR 78170). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be consistent with the Freedom of Information Act (FOIA) and FDA's published regulations of "*Public Information*" under 21 CFR Part 20. Inspectors may copy records as part of an inspection of a blood establishment. This information is for internal use and may be subject to, in whole or in part, FOIA and applicable FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Respondents to this collection of information are establishments that manufacture Whole Blood and blood components intended for transfusion. FDA believes that the information collection provisions mentioned in the guidance document for establishments to notify consignees and for the consignees to notify the blood and blood component recipient's physician of record do not create a new burden for the respondents. FDA believes that the provisions recommended in the guidance are part of the usual and customary business practice. 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. FDA believes these establishments have already developed standard operating procedures for notifying consignees and for 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 630.40 have been approved under OMB control number. 0910-0116 and 0910-0795; the collections of information in 21 CFR 606.171 have been approved under OMB control number. 0910-0458.

There is no annual hour burden estimate associated with this collection of information; however, we retain our estimate of one annual response and one burden hour to maintain the information collection provisions.

12b. Annualized Cost Burden Estimate

We estimate no annual cost burden to respondents for this collection of information.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs or operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

There are no estimated annual costs to the Federal Government associated with this collection of information.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments from the previous burden estimate. The collections of information in the guidance document are part of usual and customary business practices.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.