UNITED STATES FOOD & DRUG ADMINISTRATION

Recommendations to Reduce the Risk of Transfusion-Transmitted Infection in Whole Blood and Blood Components; Agency Guidance

OMB Control No. 0910 – 0681 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) guidance documents concerning relevant transfusion-transmitted infections (RTTIs) listed in agency regulations under § 630.3(h)(1) (21 CFR 630.3(h)(1)) and concerning the conditions under which a transfusion-transmitted infection (TTI) would meet the definition of an RTTI (§ 630.3(h)(2)). Included among the list of RTTIs under 21 CFR § 630.3(h)(1) are the following: Trypanosoma cruzi (Chagas), Creutzfeldt Jacob Disease (CJD)/variant Creutzfeldt Jacob Disease (vCJD), plasmodium species (malaria), and West Nile virus. The RTTIs FDA has identified thus far under § 630.3(h)(2) include Zika virus and babesiosis. In addition, FDA has determined Ebola virus to be a TTI identified under § 630.3(l). We have issued guidance documents with recommendations regarding the RTTIs or TTIs including Chagas, babesiosis, Zika virus, West Nile virus, Ebola virus, malaria, CJD and vCJD, human immunodeficiency virus (HIV) and human T-lymphotropic virus, types I and II (HTLV).

The Chagas, babesiosis, Zika virus and West Nile virus, and HTLV guidance documents provide recommendations for consignee and physician notification relating to donors that tested reactive for these infections. In addition, a blood establishment may receive information from a donor following collection that reveals the donor had a risk factor for a RTTI or TTI at the time of collection and should have been deferred for the risk factor. FDA has recommended, in the guidance documents, that such a blood collection establishment notify the consignee regarding the distributed blood components that are potentially at-risk for a RTTI or TTI. In some cases, we recommend that if the blood was transfused, the consignee notify the transfusion recipient's physician of record regarding the potential risk. This recommendation is included in Ebola virus, malaria, CJD and vCJD, and HIV guidance documents. The guidance documents are available from our website at https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.

The guidance documents establish donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to the RTTIs. The donor screening tests are necessary to reduce the risk of transmission of RTTIs in plasma and serum samples from individual human donors, including donors of Whole Blood and blood components intended for transfusion.

We are revising the information collection to reflect revision to relevant guidance documents. In the Federal Register of March 25, 2020 (the March 25, 2020, notice) (available at: https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf), FDA announced procedures for making available agency guidance related to the COVID-19 PHE. These procedures, which operate within our established good guidance practices regulation at 21 CFR 10.115 and provide for public comment at any time, are intended to allow FDA to rapidly disseminate recommendations and policies related to COVID-19 to industry, FDA staff, and other interested persons. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID-19 PHE, we believe that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidances. Therefore, FDA will issue COVID-19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C) and 21 CFR 10.115(g)(2) (§ 10.115(g)(2))). The guidances are available at FDA's web page entitled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders" (https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders) and through FDA's web page entitled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. The March 25, 2020, notice also stated that, in general, rather than publishing a separate NOA for each COVID-19-related guidance, we intend to publish periodically a consolidated NOA announcing the availability of certain COVID-19-related guidances FDA issued during the relevant period. We have subsequently published two such notices on May 12, 2020 (85 FR 28010) and May 26, 2020 (85 FR 85 FR 31513).

As a result of this public health emergency, there is a significant shortage in the supply of blood in the United States, which we believe early implementation of the recommendations in these guidance documents may help to address (even though the recommendations in this guidance are broadly applicable beyond the COVID-19 public health emergency). We have made revisions to the Malaria, CJD, and HIV guidance documents accordingly. As other relevant transfusion-transmitted infections are determined under § 630.3, we may continue to issue guidance accordingly, and, if approved, intend the information collection to be included under this OMB control number.

We therefore request of OMB approval of the information collection provisions found in the agency guidance documents issued related to 21 CFR § 630 (*Requirements For Blood And Blood Components Intended for Transfusion or For Further Manufacturing Use*), as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection is intended to reduce the risk of transmission of RTTIs. The notification of consignees and of the recipient's physician of record is intended to provide the necessary information regarding possible increased risk of RTTIs or TTIs. 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

There is no undue impact on small entities resulting from the information collection. We assist small businesses through resources on our website and within our Center for Biologics Evaluation and Research's (CBER) Office of Communication, Outreach, and Development (OCOD), Division of Manufacturer's Assistance and Training (DMAT), Manufacturers Assistance and Technical Training Branch (MATT) (email: Industry.Biologics@fda.hhs.gov).

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with associated regulatory requirements and recommendations found in the applicable agency guidance documents. 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 January 7, 2020 (85 FR 716). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate handling of information collected. The information collection includes personally identifiable information (PII) or information of a personal nature. The subject guidances pertaining to RTIIs and TTIs that would meet the definition of a RTII establish donor screening recommendations for the FDA approved serological test systems for the detection of antibodies to the RTIIs. Respondents to this collection of information are establishments that manufacture Whole Blood and blood components intended for transfusion. PII collected is information from donors to

determine suitability that includes contact information so the consignees and the recipient's physician of record can be notified, if necessary. We have determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected.

Inspectors may copy records as part of an inspection of a blood establishment. Establishment records describing manufacturing procedures that we may copy or take possession of during an inspection often contain trade secret and confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)); by Section 301(j) of the FD&C Act; and, by part 20 of our regulations (21 CFR part 20).

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

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 documents 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 guidances 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 licensed assays. 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.

Although such notifications are rare, we believe that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. In addition, we believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for a TTI. Therefore, for the purpose of estimating burden under the PRA, we provide a cumulative estimate of one response and one burden hour annually for the information collection attributable to the following guidance documents included in this information collection.

The guidance documents, as applicable, also refer to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number. 0910-0338; the collections of information in 21 CFR 606 and 630 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.

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, start-up, operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

We estimate no cost to the Federal Government for the collection of information.

15. Explanation for Program Changes or Adjustments

While the burden estimate remains unchanged, we have included additional guidance documents, as approved by OMB, since last approval of the information collection. We have also made certain revisions to applicable guidance documents resulting from the current PHE, as discussed in *Question 1* above.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.