United States Food and Drug Administration

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

OMB Control No. 0910-0681

REQUEST FOR NON-MATERIAL CHANGE: **Justification**

This information collection supports FDA recommendations found in agency guidance. Under 21 CFR 630.3(h), a list is set forth of relevant transfusion-transmitted infections (RTTIs) (21 CFR 630.3(h)(1)) and the conditions under which a transfusion-transmitted infection (TTI) would meet the definition of an RTTI. (21 CFR 630.3(h)(2)). The list of RTTIs under 21 CFR 630.3(h)(1) includes, among other things, the following: *T. cruzi* (Chagas), Creutzfeldt Jacob Disease (CJD)/variant Creutzfeldt Jacob Disease (vCJD), *plasmodium* species (malaria), and West Nile virus. The RTTIs we have identified thus far under 21 CFR 630.3(h)(2) include Zika virus and babesiosis. In addition, we have determined Ebola virus to be a TTI identified under 21 CFR 630.3(*l*).

Currently, recommendations for notification of blood consignees and the transfusion recipient's physician of record, intended to provide the necessary information regarding possible increased risk of *T. cruzi* infection (Chagas) in distributed blood components, are included in the agency guidance entitled "*Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion*" (the "Chagas guidance"), and approved under this ICR. The Chagas guidance recommends that:

- establishments notify consignees of all previously distributed blood and blood components previously collected from a donor that tested repeatedly reactive for the *Trypanosoma cruzi* (*T. Cruzi*) antibody; and

- blood establishments encourage consignees to notify the recipient's physician of record of a possible increased risk of *Trypanosoma cruzi* infection, if the recipient was transfused with blood or blood components previously collected from a donor who tested repeatedly reactive for *Trypanosoma cruzi* antibody.

Consistent with our good guidance practice regulations (21 CFR 10.115), we published a notice in the Federal Register of July 27, 2018 (83 FR 35657) announcing availability of the draft guidance entitled, "*Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis*," (the "Babesiosis guidance") and invited public comment. In addition, we published a notice in the Federal Register announcing the availability of the following:

- "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry" (July 9, 2018; 83 FR 31760);

- "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion" (74 FR 57685; November 9, 2009).

Like the Chagas guidance, the Babesiosis, Zika virus, and West Nile virus guidance documents provide recommendations for consignee and physician notification relating to donors that tested repeatedly reactive for Babesia. 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 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. Nonetheless, we attribute one hour of burden and one response annually for the information collection recommendations included in the Chagas guidance and the Babesiosis, Zika, and West Nile guidance documents collectively.

We are planning to finalize the Babesiosis guidance document and are requesting that its recommendations for notification be included in the approved information collection as well as the recommendations for notification contained in the Zika virus and West Nile virus guidance documents. While the Chagas, Babesiosis, Zika virus, and West Nile virus guidance documents discuss recommendations specific to each RTTI, they all include the same usual and customary information collection activity for respondents.

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 following 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. We published notices in the Federal Register announcing availability of these guidance documents as follows:

- Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry (82 FR 3002; January 10, 2017)

- Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry (81 FR 1957; January 14, 2016)

- Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria - Guidance for Industry (78 FR 50421; August 19, 2013)

- Revised Recommendations for Reducing the Risk of Human Immunodeficiency (HIV) Virus Transmission by Blood and Blood Products; Guidance for Industry (80 FR 79912; December 23, 2015)

We are including the recommendations for consignee and/or physician notification contained in the guidance documents for Ebola virus, CJD/vCJD, HIV, and malaria, as noted above, in this request..

As other relevant transfusion-transmitted infections are determined under 21 CFR 630.3, we may continue to issue guidance accordingly, and, if approved, intend the information collections to be included in this ICR.

December 2018