Advancing Transfusion and Cellular Therapies Worldwide

America's Blood Centers® It's About Life.

American Red Cross

08 February 2017

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via http://www.regulations.gov

Re: Docket No. FDA–2009–D–0137, "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the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion Draft Guidance for Industry," 10 November 2016.

Dear Dockets Manager:

AABB, America's Blood Centers (ABC) and the American Red Cross (ARC) appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) on the draft guidance titled "Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and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." These comments were prepared by a working group of member experts from AABB's Donor History Task Force and Transfusion Transmitted Diseases Committee, which includes representatives from ABC and ARC.

Our organizations support the FDA's draft recommendation that one-time testing alone, without donor questioning for a history of Chagas disease, is adequate to identify donors at risk for transmitting *Trypanosoma cruzi* (*T. cruzi*). We support FDA's recommendation

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for one-time donor testing with the resulting deferral, supplemental testing, and counseling for a donor testing repeatedly reactive on a licensed test for antibody to *T. cruzi.* We have included one recommendation regarding consolidation of recommendations related to *T. cruzi.*

Comments to specific a recommendation are arranged in the following format:

> **Section** – language from the draft guidance reprinted.
> **Recommendation or Request for Clarification** – recommendation or clarification request.
> **Rationale/Supporting Information** – rationale in support of the recommendation /clarification request.

Section –
III. RECOMMENDATIONS
The recommendations set forth below are intended to update the recommendations in FDA's 2010 Chagas Guidance at section III.A and section III.C. The recommendations regarding product management in section III.B of the 2010 Chagas Guidance are unchanged.

Recommendation –
We recommend all relevant information be included in final guidance document to provide the most effective resources to blood establishments.

Rationale/Supporting Information –
In addition to new recommendations contained in section III of this document, the draft guidance makes multiple references to the information in the 2010 Chagas guidance. For example, the introduction states that FDA will "amend the document titled "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." It also states that when finalized, FDA will "update the 2010 Chagas Guidance by incorporating the new recommendations provided in this guidance into an updated final guidance. All other recommendations in the 2010 Chagas Guidance will remain unchanged." This question arises because the language used by FDA does not specifically state FDA's intention to place all final recommendations on *T. cruzi* in the final guidance. For instance, the recommendations regarding product management in section III.B of the 2010 Chagas Guidance (referenced above) do not appear in the guidance released in November 2016.

We believe consolidating all current recommendations in the final guidance is the best practice for updating and expanding the scope of the 2010 Chagas Guidance. The less effective option to leave recommendations in multiple guidance documents creates an opportunity for error that could, and should be, avoided in a complex regulatory environment.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments. We look forward to continuing to work with the FDA on patient and donor safety initiatives. Questions concerning these comments may be directed to SCarayiannis@aabb.org.

Sincerely,

Sharon Carayiannis
Deputy Director
Regulatory Affairs