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June 24, 2009

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

Re: Docket No. FDA- 2009-D-0137

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the draft guidance Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma Cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS

This is a well written document that provides useful information for regulated industry. Finalization of the guidance will be welcome and important because there is a great potential impact of communicable diseases, such as *T. cruzi*, on a product that is scaled up through manufacturing and may be distributed to millions of recipients (e.g., an allogeneic cell based product).

We note that although it is possible to determine the existence of serum antibodies suggesting chronic infection, donors who have acute infection with *T. cruzi* may not be identified by the test. Therefore (as we also note in our specific comments below), it is important to mitigate risk by taking a relevant medical history as well as screening peripheral blood smears for the presence of trypomastigotes, blood cultures for *T. cruzi*, and blood for the presence of DNA by PCR, or by requiring re-testing of live donors for serum antibodies after a specified period of time (e.g., 1 month).

The comments provided below are specific to HCT/Ps and do not address whole blood and blood components for transfusion.

SPECIFIC COMMENTS

Specific Comments			
Citation Location Section/Page	**Relative Impact ***	**SPECIFIC Concern (short explanation)**	**Proposed Change (if applicable)**
III, Sections A and B	C	It is unclear to the reader why there are significant differences between whole blood and blood components for transfusion & HCT/Ps with regards to testing for the presence of T cruzi. Specific donor and product management activities are required for blood but not HCT/Ps.	Please clarify why the recommendations for these product types are 'different' in the introduction (Section I) or in the background (Section II).
III, Section B, 2, bottom of page 8	E	The last sentence on page 8 is discontinuous.	Please complete the sentence.
IV, Sections A and B	C	These sections do not contain recommendations to protect a recipient of HCT/Ps from a donor with acute infection.	For live donors of HCT/Ps, the guidance should recommend risk mitigation for acute infection. This could include taking a relevant medical history and detecting subjects with acute infection either by conducting additional tests (e.g., blood smears, blood cultures and PCR) or requiring

			re-testing for serum antibodies after a specified period of time (e.g,, 1 month). The latter is not applicable for cadaveric donors.

*** Relative Impact** **C** = A critical concern that must be addressed
M = A minor concern that should be addressed
E = Editorial comment to text (change not necessarily required)

CONCLUSION

Once again, we appreciate the opportunity provide comment. We would be pleased to clarify or expand our comments, as needed.