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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Reference: FDA Docket #00D-1267: Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria

Sirs:

America's Blood Centers (ABC) is an association of 75 community blood centers responsible for approximately half of the US volunteer donor blood supply. We appreciate the opportunity to comment on the Center for Biologics Evaluation and Research's draft guidance for industry, "Recommendations for Donor Questioning Regarding Possible Exposure to Malaria."

ABC shares FDA's commitment to minimizing the risks of transfusion. We also wish to remind FDA that the Centers for Diseases Control and Prevention consider transfusion-transmitted malaria to be rare. Of the reported cases of transfusion-transmitted malaria, most resulted from donation by donors who have lived in or were born in areas endemic for malaria. On the other hand, only four cases from Mexico and/or the Caribbean have been reported since 1963, none of which resulted from visits to resort areas. Yet because of the proximity of the United States to Mexico and the Caribbean, every year thousands of vacationers to resorts and their surrounding environs in the region are deferred. ABC encourages FDA to focus deferral efforts on excluding donors shown to be truly at high risk for transmission of malaria while relaxing strict deferral policies for donors who vacation in these popular resorts—none of whom have ever been responsible for a single reported case of transfusion-transmitted malaria.

With regard to the proposed new questions, ABC believes that—as worded—they will fail to identify the high risk group intended and will worsen the already complicated donor screening process. Screening donors at risk for malaria transmission already is complicated and confusing—as shown by the high rate of post-donation incident reports. Although it often is assumed that post-donation incidents reflect failure to perform donor screening properly, in fact, a large part of the failure is due to the complexity of dual criteria: FDA's criteria for donor deferral vs. CDC's criteria for malarial prophylaxis and significant confusion regarding what constitutes "rural" versus "non-rural." As long as inconsistencies and complexities in the use of the *Yellow Book* exist, it is unlikely this situation will be resolved. Furthermore, ABC is a participating organization of the Donor History Questionnaire Interagency Task Force charged to evaluate current infectious disease questions in view of recent scientific data, to identify

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and reword questions with difficult and/or confusing wording and to evaluate methods to validate current and proposed donor screening questions. ABC urges FDA to allow this task force to complete its mission prior to adding new questions to the mix.

In attempting to revise the malaria guidance to identify those persons truly at risk for transmitting malaria, FDA has placed the focus on place of birth. ABC is concerned about the insensitivity to immigration issues such a line of questioning engenders and, as an alternative proposes the alternative line of questioning outlined below. This approach is more likely to identify the targeted risk group of persons who may have partial immunity to malaria and may need a longer deferral period. It also has the added benefit of retaining the current question while adding no new questions.

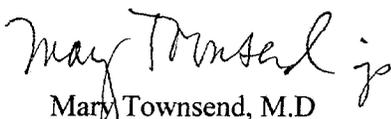
ABC Proposes the following Single Donor Question with Follow-up. (Also see Attachment I (flow chart))

Question: *In the past 3 years, have you been outside the United States or Canada?*

- NO Accept the Donor
- YES Document destination(s) of travel, date(s) of travel, date(s) of departure
 - *Is any area visited determined to be endemic for malaria?*
 - NO Accept Donor
 - YES Determine if the donor has lived outside the United States or Canada for more than 5 years
 - NO Donor is acceptable 12 months after date of departure
 - YES Document where the donor resided and determine if the area in which the donor lived was endemic for malaria
 - NO Defer for 12 months from date of departure
 - YES Defer for 3 years from date of departure

Thank you for the opportunity to comment. I would be pleased to answer any questions you might have about our comments.

Yours Truly,



Mary Townsend, M.D
Chair, Scientific, Medical and Technical Committee
America's Blood Centers

Attachment 1: Recommended Questions for Donors About Travel to Malarial Areas

