

**San Diego  
Blood Bank**  
A Regional Blood Center

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August 17, 2000

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

**Re: Docket No. 00D-1267: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria**

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To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's (FDA) proposed guidance "Recommendations for Donor Questioning Regarding Possible Exposure to Malaria."

San Diego Blood Bank (SDBB) is concerned about the implications resulting from recommendation number 4: "Persons that may possess a partial acquired immunity to malaria, such as those that have previously resided in a malarious region for at least five years (immigrants, refugees, citizens, persons who have been or who are residents of endemic countries), should not be accepted as donor of Whole Blood or Blood components, including platelets, for a period of three years since their last visit to a malarious region". This statement says that any person currently living in an endemic **country** is excluded from donating, even if they do not live in an endemic region, and have not visited an endemic region. This type of exclusion could adversely affect the supply of blood in our region, without increasing the safety of the blood supply. There is no reason to believe a healthy individual living in a non-endemic portion of country that has some area of malaria risk is at risk for malaria. By definition, no one in the US should donate, because parts of the US could be considered to be endemic for malaria. SDBB suggests deleting this statement from the guidance.

SDBB would like clarification of the statement "keep pace with the CDC yellow book" noted in the background portion of the guidance. What does "keep pace" mean? Is having the most current revision of the yellow book keeping pace? Will CDC notify blood centers when guidelines change? Does this mean the guidelines will only change annually, when the new revision is published?

00D-1267

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SDBB disagrees with the proposed donor questions as stated in the guidance as being too confusing for the donors, and redundant in some cases. Asking a donor if they were born in the US, getting an answer of yes, and then asking them if they were born in the following African countries will not give donors a sense of confidence in the blood center, but give the impression the blood center is confused. The following two questions are suggested as an alternative approach:

Question 1: "Have you traveled or been outside the USA including Canada or Mexico in the past twelve months?"

If the donor says no, go to question 2

If the donor says yes, the screener would then find out what countries the donor had been to, and evaluate for malaria risk.

If the donor had been to a malaria area, determine length of stay and defer for 12 months or three years as appropriate.

If no risk then go to question 2.

Question 2: "Within the past three years, have you lived (for 5 years or more) outside the USA, including Canada or Mexico?"

If the donor say no, accept donor

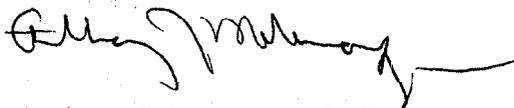
If the donor says yes, the screener would find out what counties and evaluate, depending on malaria risk.

If the donor had been to a malaria area, then defer for three years.

If donor had not been to a malaria area, then accept donor.

Thank-you for this opportunity to comment on FDA's notice "Recommendations for Donor Questioning Regarding Possible Exposure to Malaria." If you have any questions, please feel free to contact me or the Director of Quality Assurance/Compliance, Ms Patricia E. Bakke, at 296-6393, or by e-mail to [tmelaragno@bloodbank.org](mailto:tmelaragno@bloodbank.org) or [pbakke@bloodbank.org](mailto:pbakke@bloodbank.org).

Sincerely,



Anthony J. Melaragno, M.D.  
Medical Director/CEO  
San Diego Blood Bank

# San Diego Blood Bank

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