

**San Diego
Blood Bank**
Saving Lives Since 1950



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July 3, 2002

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

Re: Docket No. 02D-000: Draft Guidance for Industry-Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires.

To Whom It May Concern:

San Diego Blood Bank (SDBB) appreciates the opportunity to comment regarding streamlining the donor screening process. We appreciate your efforts to draft guidelines for our industry to follow. We are concerned, however, that some of these guidelines may actually hinder the process rather than help it. Our concerns are outlined below.

Part III, Section A, number 4 says that we should not allow new donors to self-administer the donor questionnaire. Currently, the classic form of questioning includes the donor self-administering sections of the donor questions (health history) and a screener verbally asking high-risk questions. Your document would seem to prohibit this practice. We would like this section clarified to assure that the document would allow donor centers to continue their current practices.

Part III, Section A, number 9 requires that all new or revised questions be provided to donors by direct oral questioning or with a detailed description of the changes. We do not believe this is a feasible requirement. There is no definition of how long a question is "new" or how long information regarding modifications would need to be provided. We would suggest that updated educational materials be presented to donors at each donation visit to assure the donor has access to all pertinent information, whether changed or not.

Part III, Section B, number 5 requires that donors be monitored for attentiveness if the donor is using audio or visual tools for donor screening. We believe that this may inhibit the donor since privacy is not assured. We would suggest that the donor be instructed to speak with the collection staff if they are confused or have any questions.

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Part III, Section C, number 1 requires that new donors may only use computer-assisted procedures provided there is an audio component. We do not agree with this requirement. No audio component is required if a donor manually answers all of the questions using paper methods, so we respectfully request this requirement be deleted from this section.

Part IV, Section A, number 2 requires that a PAS be submitted if computer-assisted interactive procedures are used. The FDA allows a blood center to completely replace a current computer system and notify the FDA via the annual report. We would suggest that the same mechanism be used when implementing a new computer procedure in just one area of the blood center.

Thank you for this opportunity to comment on FDA's notice " Draft Guidance for Industry-Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires." If you have any questions, please contact Ms. Patricia E. Bakke, Director of Quality Assurance/Compliance, at 619-400-8254 or me at 619-400-8222. E-mail addresses are pbakke@bloodbank.org or rwalker@bloodbank.org

Sincerely,



Ramona L. Walker
Chief Executive Officer

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