

San Diego
Blood Bank
Saving Lives Since 1950



September 20, 2001

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

Re: Docket No. 97D-0318: Draft "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products."

To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's (FDA) draft guidance entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products;" announced in the Federal Register on August 29, 2001.

San Diego Blood Bank requests clarification on the use of the phrase "Whole Blood Donors". Is it your intent to exclude apheresis donors from this guidance, those donors who donate apheresis Red Blood Cells, Plasma or Platelets for transfusion, as you are excluding Source Plasma?

In Part D, you are suggesting that all donors who are hearing the questions relating to vCJD risk for the first time be subjected to a face-to-face interview due to the complexity of the questions. We would like to offer an alternative approach. We are suggesting that repeat donors continue to answer questions via a self administered questionnaire, but that the new questions (in whatever final form that may be) be specially designated as "NEW QUESTION" on the donor record, or italicized, or otherwise called attention to. Blood centers should be offered that approach along with displaying materials that would alert repeat donors to the new questions. Trying to determine if a donor has ever seen a question before may not be possible in many circumstances, such as mobile areas or small blood centers without computer systems, and would be fraught with error.

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Additionally, because the suggested questions are so complex, donors need time to read the questions and determine if they fit any of the risk criteria. To verbally ask these very complex questions may not be an effective means. The donor will have to read them anyway. An alternative approach is to simply ask "Have you been out of the country since 1980? If the donor

answers "yes", they could document the areas visited and amount of time they spent in each area. The screener would then evaluate and ask additional questions to determine if the donor was at risk.

Thank-you for this opportunity to comment on FDA's draft "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products." If you have any questions, please feel free to contact me or the Director of Quality Assurance/Compliance, Ms Patricia E. Bakke, by phone at 296-6393, or by e-mail at rwalker@bloodbank.org or pbakke@bloodbank.org.

Sincerely,

A handwritten signature in cursive script that reads "Ramona L. Walker". The signature is written in black ink and is positioned below the word "Sincerely,".

Ramona L. Walker,
Chief Executive Officer
San Diego Blood Bank

CERTIFIED MAIL

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

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