San Diego
Blood Bank
Saving Lives Since 1950

April 25, 2003

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

Re: Docket No. 03D-0163, "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS."

To Whom It May Concern:

San Diego Blood Bank appreciates the opportunity to comment on the "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS", published April 23, 2003.

Section III, part A. Donor Interview Questions

San Diego Blood Bank does not believe that asking additional questions is an effective method for identifying donors that may have been exposed to SARS. The donor questions are already over 40 questions long, and we feel it is important to concentrate on known donor risks. The more questions we add increase the chance of confusing the donor, and perhaps missing critical information that would impact the safety of the blood. We suggest that a more effective means would be to inform the donors at risk for SARS not to donate for 14 days after returning from a SARS implicated area. Waiting until they present at a donor center is counterproductive.

It does not appear that the example questions were reviewed by the AABB Uniform Donor History Questionnaire task force. This task force has the ability to review and analyze questions to determine if they meet criteria for donor comprehension. We request that all additional questions be referred to the task force prior to being included in guidance documents.

Additionally, you are requesting that all blood collection centers "routinely and periodically" refer to the CDC website for updated information regarding case definitions. This statement, at best, is difficult to interpret. Must we review the site daily? Weekly? Monthly? If the site was viewed daily, then how long do we have to update our staff at all of our donor centers? The logistics of **effectively** and accurately notifying staff can be overwhelming even if changes do not occur very often. We suggest that any changes be issued by the FDA through routine channels.

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Part C, 4 Notification of State of Local Agencies

We do not believe that a blood center is the appropriate agency to report cases of SARS to health agencies. We do not have the ability to diagnose donor or blood recipients. As with other communicable diseases, the responsibility belongs with the diagnosing physician and the mechanism for reporting already exists .

Part V, Implementation

We do not believe that 30 days is sufficient time to implement the elements of this guidance. In addition to the changes necessary to our donor card, pre-donation literature, standard operating procedures, and training documents, we must also translate the questions into Spanish. We are asking that when your agency believes that additional questions are necessary, that you include the example questions in other commonly used languages in your guidance. This would facilitate implementation, and provide assurances that all centers using other languages are translating the same.

General comments:

At the present time, SARS has not been implicated in any transfusion associated disease case, nor has there been any evidence to support the probability that SARS can be transmitted by blood products, but this guidance was issued as a final guidance without input from blood transfusion experts within our community, or to the Blood Products Advisory Committee. We would request that this guidance be updated to "draft" to allow time for review and comment from blood organizations, other FDA committees and other interested parties.

We appreciate this opportunity to comment on the "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS". If you have any questions, please feel free to contact Ms. Patricia Bakke, Director of Quality Assurance/Compliance, or me, at 619-296-6393.

Sincerely,

Ramona L. Walker
Chief Executive Officer

rlw/peb