COMMUNITY BLOOD CENTER
OF THE OZARKS
a not-for-profit organization

April 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm.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:

The above referenced FDA guidance appears to have been the result of the need for an immediate reaction to the SARS outbreaks.

We agree with the need for immediate action. We think that such action can be taken after consultation with industry experts. Technology is available today (i.e. e-mail, conference calls, etc) to get input from many sources the same day or the next day. BPAC can be convened using such technology for an emergency meeting.

At the time of issue of the guidance, "about 95%" of the cases had traveled to outbreak areas. By addressing travel to an indicated SARS area and temporarily deferring these donors would have addressed the immediate known concerns.

Blood centers currently have questions to identify donors who: a) are not feeling well, b) have a fever, or c) have been under a physician's care. These questions would elicit the same information as the first recommended question. "In the past 28 days, have you been ill with SARS or suspected SARS?"

We have discussed in several forums the burdensome task required of blood center interviewers to keep the donor alert when asking multiply questions. Now we are adding

03D-0163 C 5

Springfield
2230 S. Glenstone • Springfield, MO 65804
(417) 227-5000 • Fax (417) 227-5400
(800) 280-5337

Joplin
Joplin Center • Concorde Plaza
2639 East 32nd Street • Joplin, MO 64804
(417) 626-8323 • Fax (417) 626-8141

Springdale
Northwest Arkansas Center
5204 S. Thompson, Suite F • Springdale, AR 72764
(479) 927-1200 • Fax (479) 927-1203

three more questions to the list. We understand the Donor History Questionnaire Task Force was not consulted on the wording of the additional questions. Why not?

The frequency of post donation information being reported by donors is evidence that donors are unable to stay focused on the questions and provide accurate information.

Recommending that collection facilities,"routinely and periodically refer to the CDC website" for updates puts an added burden on blood centers to implement changes on sometimes a daily basis. If there is an update listed today, are we expected to add the country prior to collecting units today? Blood centers can not make changes daily and maintain current Good Manufacturing Practices.

The Guidance recommends that we consider notifying treating physicians when we have post donation reports of exposure to SARS or illness with SARS. It is not feasible or appropriate for blood centers to determine on the phone if a donor has developed SARS or been exposed to SARS. A more reasonable approach would be for diagnosing physicians to advice patients not to donate blood for the appropriate amount of time.

The recommendation to report cases of SARS in either donors or blood recipients to state or local public health departments and contact CDC Division of Viral and Rickettsial Diseases is also not feasible or appropriate for blood centers for the same reason as above. Blood Centers are not in the business of diagnosing diseases.

We hope the FDA will be more judicious in the issuance of future guidances and follow a logical and systematic approach that allows comments from the public prior to issuing a final guidance.

We appreciate the opportunity to comment on this guidance.

Sincerely,

Don Thomson
Executive Director

DT/jr

COMMUNITY BLOOD CENTER
OF THE OZARKS
a not-for-profit organization

April 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm.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:

The above referenced FDA guidance appears to have been the result of the need for an immediate reaction to the SARS outbreaks.

We agree with the need for immediate action. We think that such action can be taken after consultation with industry experts. Technology is available today (i.e. e-mail, conference calls, etc) to get input from many sources the same day or the next day. BPAC can be convened using such technology for an emergency meeting.

At the time of issue of the guidance, "about 95%" of the cases had traveled to outbreak areas. By addressing travel to an indicated SARS area and temporarily deferring these donors would have addressed the immediate known concerns.

Blood centers currently have questions to identify donors who: a) are not feeling well, b) have a fever, or c) have been under a physician's care. These questions would elicit the same information as the first recommended question. "In the past 28 days, have you been ill with SARS or suspected SARS?"

We have discussed in several forums the burdensome task required of blood center interviewers to keep the donor alert when asking multiply questions. Now we are adding

three more questions to the list. We understand the Donor History Questionnaire Task Force was not consulted on the wording of the additional questions. Why not?

The frequency of post donation information being reported by donors is evidence that donors are unable to stay focused on the questions and provide accurate information.

Recommending that collection facilities,"routinely and periodically refer to the CDC website" for updates puts an added burden on blood centers to implement changes on sometimes a daily basis. If there is an update listed today, are we expected to add the country prior to collecting units today? Blood centers can not make changes daily and maintain current Good Manufacturing Practices.

The Guidance recommends that we consider notifying treating physicians when we have post donation reports of exposure to SARS or illness with SARS. It is not feasible or appropriate for blood centers to determine on the phone if a donor has developed SARS or been exposed to SARS. A more reasonable approach would be for diagnosing physicians to advice patients not to donate blood for the appropriate amount of time.

The recommendation to report cases of SARS in either donors or blood recipients to state or local public health departments and contact CDC Division of Viral and Rickettsial Diseases is also not feasible or appropriate for blood centers for the same reason as above. Blood Centers are not in the business of diagnosing diseases.

We hope the FDA will be more judicious in the issuance of future guidances and follow a logical and systematic approach that allows comments from the public prior to issuing a final guidance.

We appreciate the opportunity to comment on this guidance.

Sincerely,

Don Thomson
Executive Director

DT/jr