

December 5, 2003

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

RE: Docket 03D-0163, “Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS” ? Final Guidance, September 18, 2003

Dear Docket Officer:

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

The AABB is appreciative of this opportunity to provide comments on the “Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS” final guidance. Some of these comments were presented at the June 2003 Blood Products Advisory Committee (BPAC) meeting and are being submitted to the official docket via this communication.

On April 23, 2003, the FDA suddenly issued its final guidance on SARS-related blood deferrals, requiring temporary deferrals for recent travel to SARS-affected areas, contact with a person who had probable or suspected SARS, or illness due to SARS. The FDA proposed the addition of a minimum of three additional donor history questions, which are complex and difficult to understand.

There was no effort to consult blood banks about donor comprehension and understanding of these questions, nor was there an understanding of the difficulty of adding new questions to donor questionnaires within a 30-day implementation period. As a response to these concerns, the blood banking community quickly developed an alternate proposal to present these questions using an information sheet. Fortunately, the FDA showed flexibility in agreeing to permit this alternate method, but the time to devise the alternate approach and secure FDA approval further strained the ability of blood banks to implement the guidance within the prescribed 30 days.

On September 18, 2003, FDA issued “Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS,” Final Guidance. This document supersedes the final guidance that was issued on April 23, 2003. The September recommendations defined parameters within which the travel and illness questions should be asked and how a blood center could determine that it is appropriate to stop asking the questions.

The new FDA guidance continues to advise that blood banks consult the CDC Web site to obtain updated information on SARS-affected areas and the case definition of SARS, and to update their travel deferral accordingly. However, the CDC Web site contains many definitions used for many different purposes and is very difficult to interpret. Blood center staff must wade through definitions of travel alert vs. travel advisory and decipher the difference in days counted as “incubation period.” The CDC Web site is posted with information relating to a 10-day incubation period, yet the FDA guidance recommends that blood centers use 14 days.

Further, the instruction for each blood collection facility to monitor this Web site routinely and periodically, and make changes in procedures and information sheets each time the information changes, demonstrates a major lack of understanding of blood bank operations. “Routinely and periodically” is not defined and is extremely difficult to interpret. Such a procedure is very impractical. During the recent SARS epidemic, the CDC Web site was changed frequently and at sporadic times of the day. CDC has understandably posted changes to the Web site to meet CDC needs, without appreciating the impact such changes would have on blood collection.

While we appreciate FDA’s attempt to be flexible and create a mechanism for blood centers to respond rapidly to changes in information, the current recommendations are difficult for blood centers to implement and creates a system where policy is likely to be misinterpreted and errors are very likely to occur, therefore leading to patient safety concerns. It puts the burden of interpretation on individual blood establishments, rather than on the FDA.

Before a change in procedure is implemented at a blood collection facility, the SOP must be rewritten and the staff trained. In the case of donor suitability, this involves training of large numbers of staff as well as preparation of new donor history questionnaires and donor materials. **Please clarify FDA’s current thinking on what is an appropriate allowance of time for a blood center to implement these steps, while working in a cGMP framework, given that on some occasions the posted information has changed from one day to the next.**

The AABB and other blood banking organizations from the outset shared FDA’s concerns about the possibility of transmission of SARS through the blood supply. Beginning in April of 2003, the AABB convened the first of several conference calls with other blood banking organizations and invited the CDC and FDA to participate in the discussions. At that time, the task force requested that CDC include information about blood donation deferral on the SARS information cards that were being distributed to travelers returning from SARS-affected areas. The rationale for this request was that this would be a targeted, and therefore, better way to reach affected individuals than requiring changes to donor history questionnaires and asking questions of millions of potential blood donors annually. However, when it was quickly obvious that this recommendation was not going to be adopted, the blood banking community agreed that deferral of travelers returning from a SARS-affected area should be implemented. We also discussed the possibility of deferring donors who might have had contact with SARS, and concluded that such

deferral was not indicated. During these task force discussions, we specifically queried FDA about measures they might be planning, and were told that they were unable to provide any information, but that our plan of action would not be contrary to FDA thinking. We understand that FDA is constrained by the Administrative Procedures Act, but their inability to hold discussions with the blood banking community is certainly not in the best interests of patient and donor safety.

In conclusion, the AABB is concerned about the safety of patients and donors. We recognize that new infectious agents require policy decisions to be made, sometimes before all of the scientific information is available. The blood banking community has demonstrated that it can be convened on very short notice, and stands ready to interact with FDA as needed. Early interaction would permit devising recommendations that are practical and possible to implement, and would avoid needless confusion. It would also avoid the need to submit alternate procedures for FDA approval and thus permit blood banks to begin planning for implementation in a timelier manner. While we appreciate the need to respond to a perceived threat to the blood supply, the AABB requests development of a mutually satisfactory approach to improve FDA recommendations so that the most appropriate and effective interventions can be established on behalf of patient safety and blood availability.

Finally, on issues specific to SARS, we request that FDA and/or CDC initiate studies to determine whether there is viremia during the asymptomatic period of SARS. This information is vital in deciding whether these donor deferral criteria should be continued.

Questions concerning these comments may be directed to M. Allene Carr-Greer, Deputy Director, Regulatory Affairs, AABB (acarrgreer@aabb.org).

Sincerely,

Karen Shoos Lipton, JD
Chief Executive Officer