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May 24, 2004

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

Docket No. 2004D-0192

To Whom It May Concern:

Listed on below (Attachment I) are our comments regarding the document *Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components*.

The document is concise and clearly written. The use of flow charts is most helpful and the FDA should include such aids in all future guidance dealing with complex issues such as donor questions, donor re-qualification, testing algorithms, etc.

Because this questionnaire represents a substantial improvement over the current Uniform Donor Questionnaire, the FDA is encouraged to release a final guidance to allow implementation as soon as possible.

It is hoped that a similar guidance will be forth coming to allow the use of an abbreviated questionnaire in repeat donors.

On May 20, 2004 CBER issued the final rule and draft guidance entitled for *Eligibility Determination of Human Cells, Tissue, and Cellular and Tissue-Based Products*. As an establishment that collects both donors for blood and blood components and cellular-based products, we compared these documents with the donor questionnaire document and noted some inconsistencies (Attachment II).

Thank you for your consideration of our comments in formulating the final rule.

Sincerely,

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Division Chair, Transfusion Medicine
Mayo Clinic Rochester

cc: Jeffrey Winters, M.D.
Mary Foss
Sheryl Tran

2004D-0192

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Question		Comment
6	In the past 48 hours have you taken aspirin or anything that has aspirin in it?	Current requirements restricts aspirin use to 36 hours. Was this intentionally changed?
7	In the past week, have you had a headache and fever at the same time?	There is an inconsistency between the Donor Eligibility information and the flow chart. The Donor Eligibility information states "...should not donate for 7 days after resolution", however the flow chart indicates a donor with an affirmative response should be deferred for 28 days.
9	In the past 8 weeks have you donated blood, platelets, or plasma?	We would like to add a line below this question for the donor to record the date of donation and the product donated. Would this modification comply with the intent of a uniform questionnaire?
16	In the past 12 months have you come into contact with someone else's blood?	The question and flow chart only reference exposure to someone else's blood, with no reference to exposure to other types of body fluids. Was this intentionally omitted?
23	In the past 12 months have you had sexual contact with a person who has hepatitis?	The flow chart as written requires a 12 month deferral after last sexual contact with an individual with Hepatitis A. This seems excessive given the fact that a chronic carrier state does not occur with this disease and that the incubation period for the illness is well known. With an incubation period of 15 to 50 days (mean 30) and fecal shedding/viremia for 18 days after onset of illness, it would seem more appropriate to defer a donor for a much shorter period of time following sexual contact with an individual with Hepatitis A (e.g. 3 months).
25, 26	In the past 12 months have you had a tattoo? In the past 12 months have you had ear or body piercing?	The questions and flow charts only reference tattoo, ear, or body piercing, with no reference to acupuncture. Was this intentionally omitted?
29	In the past three years have you been outside the United States or Canada?	Canada was omitted from this question with the implementation of the SARS questions in April 2003. Was Canada intentionally reinstated in this question?
31	From 1980 through 1996, were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?	We recommend the wording of this question be changed to : Were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military <i>in Europe</i> ? This addition would reduce the number of affirmative answers we receive targeting the question to the donors we are trying to identify.

Discrepancies noted between the *Acceptable Full-Length Donor History Questionnaire* document and the *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)* documents

Blood Donor Document	HCT/Ps Document
<p>Question 37 - Have you <u>ever</u> used needles to take drugs, steroids, or anything not prescribed by your document? If yes, defer donor indefinitely.</p>	<p>Page 16, E 2 - persons who have injected drugs for non-medical reason in the <u>preceding five years</u>, including intravenous, intramuscular, or subcutaneous</p>
<p>Question 34 - <u>From 1977 to the present</u> have you received money, drugs, or other payment for sex?</p>	<p>Page 16, E 4 - persons who have engaged in sex in exchange for money or drugs in the <u>preceding five years</u></p>
<p>Question 39 - Have you <u>ever</u> had hepatitis? If yes, determine how old donor was. If before 11th birthday-Accept; if after 11th birthday-Defer.</p>	<p>Page 17, E 11 - persons who have had a past diagnosis of clinical, symptomatic viral hepatitis after age 11, <u>unless evidence from the time of illness documents that the hepatitis was identified as hepatitis A</u></p>