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Sent by E-mail;
No paper copy sent

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

Re: FDA Docket 2004D-0198, Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components.

Dear Docket Officer:

America's Blood Centers appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance on the uniform donor history questionnaire (UDHQ) developed by the Interorganizational Uniform Donor History Questionnaire Task Force, under the auspices of the American Association of Blood Banks (AABB). We applaud FDA and the UDHQ Task Force for taking strong steps to rationalize the donor interview process.

We strongly support the concept of a donor history questionnaire that is straightforward to administer and reliably captures the information essential for the safety of blood donors and the blood supply. We especially welcome the scientific approach to validation of the questionnaire, and we look forward to the formal validation of questions that may be added or modified in the future.

Our specific comments on the draft guidance follow.

Flow Charts and User Brochure. The guidance states in Section IV. A. 2: "We believe that adherence to the following DHQ procedures prepared by the task force, Version No. 1 (v.DHQ-1) (Appendices 1 – 7), would provide adequate measures to meet FDA requirements related to donor eligibility." Included in the appendices is the User Brochure, which has flow charts as well as a glossary. We interpret the use of the term "adherence" to indicate that the flow charts in the User Brochure could be used as optional work aids for the collections screening staff, which can be modified as necessary by each blood center in accordance with its own processes and procedures.

Please make it clear in the final guidance that the flow charts are optional work aids that can be modified by blood centers.

We also have some technical comments regarding the flow charts and User Brochure, but first, we would like clarification regarding the process of submission. The UDHQ and supporting documents are products of the AABB Task Force, and we are hopeful that this Task Force will continue to evaluate

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Comments by America's Blood Centers**

questions and further improve the screening process by monitoring the impact of implementation of the UDHQ. Therefore, we believe it would be appropriate to address specific technical comments to the AABB and provide to the FDA our comments on the processes recommended in the guidance. This is what we have done in this submission to the docket. However, we are unsure of the appropriate way to submit technical comments on the questionnaire and User Brochure itself.

We recommend that the final guidance spell out the appropriate way to submit technical comments on the questionnaire and the User Brochure .

Completing the Questionnaire. Our members are somewhat puzzled by an apparent inconsistency of the requirement to fully complete the questionnaire when a reason for deferral is identified during the screening process. The User Brochure states (p. 10) that "All donors should be instructed to complete all questions on the questionnaire." However, FDA's previous guidance on "Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires" stated (p.4, no 7): "The donor does not need to complete the questionnaire if he or she is deferred early in the questioning process."

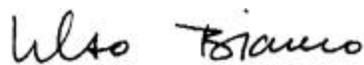
Since the Uniform Donor History Questionnaire was designed to be self-administered, these recommendations appear inconsistent. We would appreciate the resolution of this inconsistency in the final DHQ guidance document.

New Questions. ABC strongly supports the validation of new or modified questions whenever possible. We urge that the process of changing the questionnaire be as simple as possible. This process should include input from the AABB UDHQ Task Force and make it possible to design, test, and validate new questions quickly. Moreover, all parties should fully understand that implementation requires additional time to incorporate and validate procedural changes, train and assess the competency of staff, and update appropriate information systems – all in a cGMP-compliant manner.

We encourage the FDA to use the AABB UDHQ Task Force to vet any new questions being considered prior to their discussion at a BPAC meeting or publication in a guidance. The final guidance should spell out a clear path for changes and the communication of these changes to the blood collection organizations.

We look forward to continued dialogue and participation with the FDA on improving the donor screening process in order to maintain the safety of the blood supply – while making the donation process as streamlined as possible.

Yours truly,



Celso Bianco, MD
Executive Vice President