



Together, we can save a life

6 12 7 24 MS -0 1 131

August 1, 2004

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

**RE: Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components; Draft Guidance**  
**[69 FR 26399, May 12, 2004 Docket No. 2004D-0198]**

Dear Docket Officer:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Food and Drug Administration's (FDA or Agency) draft guidance titled "*Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components*" (Hereafter, referred to as *The Draft Guidance*).

The Red Cross is committed to the safety of donors and patients, and to meet the best interests of the public we serve. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs.

**The Red Cross fully supports the intent of *The Draft Guidance* to improve the donor qualification process through creation of a new and better donor questionnaire.**

From a donor perspective, current questionnaires in use by blood establishments appear complex and lengthy which can raise barriers to comprehension resulting from limited donor education levels and increasingly diverse cultural orientations. With greater demands placed on the donor population, Red Cross applauds the Agency for providing mechanisms that further the goal of making the donor interview shorter and less complex without compromising safety. According to the FDA's *Biological Product Deviation Reports- Annual Summary for Fiscal Year 2003*<sup>1</sup>:

"Post-donation information (PDI) continues to be the most common reported event for blood and plasma establishments (74.9% of reportable BPDs). In 91.9%

<sup>1</sup> <http://www.fda.gov/cber/biodev/bpdrfy03.htm#i>

2004D-0198

C4

Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components  
Docket No: 2004D-0198

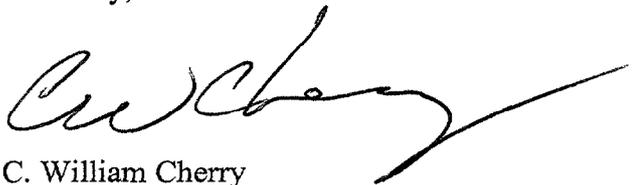
of the reports the donor was aware of the information at the time they were interviewed, but the information was not made available at that time.”

**Red Cross believes that the Agency should expedite the finalization of *The Draft Guidance* which may help reduce the incidence of post-donation information.** *The Draft Guidance* provides a new questionnaire and companion materials that were extensively evaluated by focus groups, conducted according to methods published in peer-reviewed literature<sup>2</sup>. The Red Cross has already modified its questionnaire to harmonize with *The Draft Guidance*. While we agree with the concepts of simplicity, comprehensibility, and accuracy provided in *The Draft Guidance*, Red Cross has noted several technical comments which we provide for your consideration. Please see the enclosed attachment for specific comments.

**Red Cross encourages FDA to continue to expedite development of an abbreviated UDHQ for repeat donors.** To help ensure that this vital public health resource is readily available for day-to-day use, and in the event of a domestic disaster, there will be a need for a simpler, shorter, effective donor screening questionnaire.

The Red Cross appreciates this opportunity to provide public comments on *The Proposed Rule*. If you have any further questions or require follow-up, please contact Richard S. Robinson, Director, Technical Policy and Promotions at 202-303-5867 (phone), 202-303-0103 (fax) or [RobinsonR@usa.redcross.org](mailto:RobinsonR@usa.redcross.org) (e-mail). Correspondence should be sent to The American Red Cross Biomedical Headquarters, 2025 E Street, NW, Washington, DC 20006.

Sincerely,



C. William Cherry  
Senior Vice President  
Quality & Regulatory Affairs

enclosure

CC: Kay Gregory, American Association of Blood Banks  
Michael Fitzpatrick, Ph.D., America's Blood Centers

---

<sup>2</sup> Orton SL, Virvos VJ, Williams AE. Validation of selected donor-screening questions: structure, content and comprehension. *Transfusion* 2000;40:1407-13.

Draft Guidance: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components [Docket No: 2004D-0198]

Comment #	Guidance	Comment
1)	Guidance Section IV.A.1, "Implementation of DHQ and Accompanying Materials" recommends that the documents should be implemented "...without modification and in their entirety..."	We recommend that the guidance clarify that the <u>content</u> of the DHQ and accompanying materials be implemented in their entirety, but that the <u>format</u> of the documents may be consistent with the style guide in use by the blood establishment.
2)	Appendix 2, "Donor History Questionnaire User Brochure:" "...The Educational Material and Medication Deferral List also must be used unabridged except for local additions...."	The term "unabridged" should be clarified. Allow blood establishments to change the format but not the content of educational materials.
3)	Appendix 2, "Donor History Questionnaire User Brochure," DHQ Format: "When administered by manual/paper self administration, the entire DHQ should be completed before eligibility is determined."	Donors should be allowed to stop and consult with screening staff. When donors believe that their answer may disqualify them, they are likely to leave rather than complete the form. It should be allowable, through further consultation with screening staff, to determine whether the donor is eligible.
4)	Appendix 4, DHQ Question 7: "In the past week have you had a headache and fever at the same time?"	Please clarify the deferral requirement. We recommend that the flow diagram state "defer donor per SOP" rather than "defer donor for 28 days after date of interview." The intent of this comment is to identify donors at risk for transmission of West Nile Virus, however, a trained physician should be allowed to evaluate donors who answer "yes" to this question in order to determine whether the donor should be deferred for the full 28 days from the date of the interview.

## Draft Guidance: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components [Docket No: 2004D-0198]

5)	Appendix 4, DHQ Question 9: "Is donor eligible?"	Ineligible donors should be deferred once it is determined that the donor is ineligible. We recommend that the action "Defer donor per SOP" should be changed to "Defer donor." An intermediate step of "evaluate donor per SOP" could be inserted.
6)	Appendix 4, DHQ Question 18: "In the past 12 months have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?"	We suggest that the flow chart for this question include a link referring to question 35 for cases involving male to male sex.
7)	Appendix 4, DHQ Question 21: "In the past 12 months have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrate?"	We recommend that the flow diagram should state "Defer donor per SOP" rather than "Defer donor." This will allow for Medical Director evaluation in complex cases such as hemophilia, rather than absolutely requiring deferral.
8)	Appendix 4, DHQ Question 23: "In the past 12 months have you had sexual contact with a person who has hepatitis?"	We recommend that the flow diagram should state "Defer donor per SOP" rather than "Defer donor." This will allow for Medical Director evaluation in complex cases such as hepatitis, rather than absolutely requiring deferral.
9)	Appendix 4, DHQ Question 24: "In the past 12 months have you lived with a person who has hepatitis?"	We recommend that the flow diagram should state "Defer donor per SOP" rather than "Defer donor." This will allow for Medical Director evaluation in complex cases such as hepatitis, rather than absolutely requiring deferral.

\* \* \*