



**American
Red Cross**

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June 24, 2002

Dockets Management Branch (HFA-305)
Docket No. 02D-0080
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**RE: Draft Guidance for Industry: Streamlining the Donor Interview
Process: Recommendations for Self-Administered Questionnaires (67 FR
19578; April 22, 2002) [Docket No. 02D-0080].**

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) *Draft Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires* (draft guidance).

The Red Cross, through its 36 Blood Services regions and nine testing laboratories, supplies approximately half of the nation's blood for transfusion needs. Blood donated by Red Cross volunteers is also processed or fractionated into plasma derivatives.

Donor screening is a critical step in the effort to acquire the safest blood possible and the Red Cross recognizes the importance of having a donation process that is clear, simplified and as precise as possible.

Thus, we fully support the draft guidance's intent. The Red Cross provides the attached comments in the hope that they will be constructive in aiding the development of a final guidance. Our key points are as follows:

- In the absence of data to demonstrate differences between the comprehension of first time and repeat donors, ARC requests that FDA revise the draft guidance to assure a uniform screening process by allowing all donors to use a self-administered questionnaire.

02D-0080

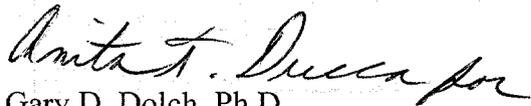
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- ARC requests that FDA reconsider the requirement to include use of an audio component for first time donors using Computer-Assisted Interactive Procedures.

- ARC requests that FDA modify areas in the draft guidance where volunteer donors may misconstrue the blood center's efforts to comply with the requirements for donor health history administration.
- ARC recommends that FDA streamline the draft guidance especially in identified sections that overlap with other regulations and/or guidances as well as requirements that we believe are unnecessarily detailed. Specific examples are included in the attached comments.

Thank you again for the opportunity to comment. If you have any questions, please contact Anita Ducca at 703-312-5601.

Sincerely,



Gary D. Dolch, Ph.D.
Senior Vice President
Quality and Regulatory Affairs
Biomedical Services

Attachment