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September 5, 2002

Dockets Management Branch (HFA-305)
Docket No. 02D-0124
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; Availability (67 FR 38505 ; June 4, 2002) [Docket No. 02D-0124].

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on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) *Draft Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion* (draft guidance).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, and as such, has a fully operative system for reporting such fatalities to the FDA. The Red Cross fully supports the draft guidance and believes that the draft guidance's specific reporting requirements are necessary and appropriate.

However, there is one aspect of the guidance that we have found may lead to ambiguous interpretation. Specifically, descriptions of the association between the fatality and the blood transfusion or donation are somewhat unclear. We recommend clarification so that there is a clear indication of the association between the fatality and the blood unit or the donation. Such clarification would help minimize unnecessary reporting while still providing FDA with appropriate information.

The draft guidance contains limited descriptions of the fatalities that must be reported. For example, the draft guidance's *Background* section cites the Good Manufacturing Practices regulations (GMPs), 21 CFR 606.170(b) as indicating that the Center for Biologics Evaluation and Research (CBER) should be notified "*When a complication of blood collection or transfusion is confirmed to be fatal...*" The only other mention of the

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association between the fatality and the donation or transfusion is found in Section IV which contains a brief reference to “*fatalities related to blood transfusions or blood collection.*”. Neither of these statements identifies the distinction between the transfusion and the blood or blood product unit(s) used in the transfusion, one of the reasons for the reporting confusion.

Out of uncertainty, our customers report deaths following a transfusion, but for which a causal association with the transfused material is uncertain, unlikely or ruled out as a cause based on additional medical information. Similarly for blood donations, the association between the donation and the fatality may be only coincidental.

The Red Cross is aware of the approaches for reporting similar fatalities used in France and in Great Britain where an ‘imputability system’ is used. These systems, the “*Haemovigilance Network*” required by law in France and the “*Serious Hazards of Transfusion,*” a voluntary system used in Great Britain, provide a scoring schema to give an indication of how likely it is the event is related to the blood unit.¹

Under the French system, for example, the hospital filing the report would include an indication of the association between the unit and the cause of the fatality based on a numerical scale from zero to four. A grade of “zero” would indicate that the death was confirmed as unassociated with the transfused materials. A “one” is unlikely to be caused by the unit, “two” would indicate a possible causal association, “three” is a probable causal association, and four means that the fatality was very likely or confirmed to be caused by the transfused materials.

We recommend consideration of one of the above or a similar system as part of the draft guidance’s reporting requirements for both transfusions and donations. Such a system should provide FDA with a greater understanding of the association between the unit or donation and the fatality. It would also simplify data analysis of trends. Finally, it would provide the blood industry and those performing the transfusions with clearer guidance regarding identification of reportable circumstances, simplify the development of the reports’ contents, and aid greater reporting consistency.

The system would need modifications to meet the United States regulatory and statutory authorities. For example, the French system is hospital-based rather than manufacturer-based as in the US regulatory structure. However, if FDA were interested, we would be pleased to work with them on such a potential grading system by suggesting grading criteria or other technical input.

With regard to timing of the reporting requirements, the Red Cross believes that the draft guidance’s reporting should be implemented as soon as it is determined that the blood unit or blood collection was involved in causing the fatality. We ask FDA to consider timing the

¹ Both systems were recently discussed at the August 25th meeting of the International Society of Blood Transfusion in Vancouver, British Columbia, Canada. The laws cited at this conference included 93-5 du Janvier 1993, 98-535 du 1er Juillet 1998 and Article 1210-12.

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