American Red Cross

Together, we can save a life

November 9, 2001

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

RE: Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments [66 FR 42546, Aug. 13, 2001 Docket # 01D-0220]; and Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components [66 FR 42547; August 13, 2001 (Docket # 01D-0221)]

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) two draft guidances on Product Deviation Reporting referenced above.

The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. The blood donated by Red Cross volunteers is also recovered and processed or fractionated into plasma derivatives. In all, the Red Cross collects approximately 1.2 million liters of recovered plasma, accounting for about 20 percent of the nation's supply of plasma derivatives.

The Red Cross is committed to the safety of our donors, our patients, and the public we serve. Thus, the Red Cross fully supports both the Deviations regulation (65 FR 66621, November 7, 2000) and these two guidances, which give further assistance in interpreting the regulatory requirements.

ARC has found these two guidances to be well written with a clear articulation of the Agency's expectations. Further, we believe that these guidances could be finalized as they are written in draft and recommend final publication as expeditiously as possible. The Red Cross has a comment that is limited to requesting clarification on a specific point of interpretation.

Our first comment has to do with Section IV of the Draft Guidance for Blood and Plasma Establishments, which contains examples of reportable and non-reportable events. Specifically, Section IV.A.(1) discusses reportable events based on Post Donation Information and indicates, "It is also reportable if the medical evaluation reasonably suggests that the safety, purity or potency of the product could be affected...".

The Red Cross interprets this section to mean that should the blood establishment become aware of post donation information and, after conducting a medical evaluation, determines that a product withdrawal is necessary, then the establishment should report the event. It is also our interpretation that if the medical evaluation indicates a market withdrawal is *not* necessary, then the event would *not* be reportable.

Should FDA's interpretation differ from ours, we recommend modification of the draft guidance to be consistent with the Red Cross view, i.e., when a medical evaluation of post donation information indicates that a market withdrawal is not warranted, the event does not need to be reported. Such modification will enable blood establishments and the Agency to focus safety efforts and data analysis on events of clearly defined concern.

The Agency also requested industry suggestions on the management of blood units that contain blood clots or are hemolyzed. The final regulation regards distribution of blood that is hemolyzed or clotted, regardless of whether it occurs with segments attached or in a clotted or hemolyzed unit, as reportable as a Biological Product Deviation. Additionally, the draft guidance does not define the term 'hemolysis' or 'clot'. We believe that the agency should require reporting when hemolysis or clotting has an affect on the product or is the result of an error. The points that we wish to make are that:

1. There is a certain amount of hemolysis that occurs during the life expectancy of a red cell or whole blood component that is due to red blood cell cessation.
2. Clotted segments without accompanying clots in the red cell component do not affect the red cell product and therefore should not be reportable.
3. Red cell products with small clots where the transfusion is completed should not be reportable.
4. Red cell products with large clots should be reportable.
5. Red cell products with hemolysis in the unit, without an identified error *in the storage or handling* of the product, should not be reportable.
6. Red cell products with hemolysis in the segments only, without accompanying hemolysis in the red cell product, should not be reportable.
7. Red cell products with hemolysis that are reported to the blood center after the hospital has accepted the unit and had the product on their shelves for several days should not be reportable by the blood center.

ARC wishes to also point out that any issue regarding gross hemolysis or bacterial contamination with accompanying hemolysis is and would always be reported.

The Red Cross appreciates the Agency's efforts to clarify and communicate their expectations regarding the Deviations reporting regulation and this opportunity to provide public comments on these important draft guidances. If you have any further questions or require follow-up, please contact Anita Ducca, Director, Regulatory Affairs at 703-312-5601 (phone), 703-312-5816 (fax) or DuccaA@usa.redcross.org (e-mail).

Sincerely,

Gary Dolch

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