



**American  
Red Cross**

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

**RE: Development of Plasma Standards Public Workshop [Docket No. 2004N-0539]**

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) public workshop titled "Development of Plasma Standards" (Hereafter, referred to as "the Workshop") held August 31 and September 1, 2004. On January 3, 2005 (*FR* 70: 92-93), FDA announced the opening of a docket to receive comments on the subject of plasma collection, freezing, and storage in addition to comments on the presentations and discussions that took place at the Workshop.

The Red Cross is committed to the safety of volunteer blood 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 plasma separated from Whole Blood is processed into Fresh Frozen Plasma (FFP) or Plasma Frozen within 24 Hours (FP24), or shipped for further manufacture into plasma derivatives. Red Cross also collects FFP concurrently with Platelets, Pheresis.

The Red Cross fully supports the intent of the Workshop to develop standards for Plasma. At the June 13, 2002 Blood Products Advisory Committee (BPAC) meeting, BPAC recommended that FDA develop standards to allow licensure of Recovered Plasma. FDA convened the Workshop in order to help determine what those standards should be.

Red Cross agrees with FDA's approach to the development of standards for Recovered Plasma and other Plasma blood components. ARC has reviewed transcripts from numerous BPAC meetings, including June 2002, June 2003, December 2003, March 2005, and transcripts and presentations from the Workshop. The following themes recur throughout these discussions:

1. FDA wishes to develop science-based requirements for plasma processing, freezing, and storage.

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*Together, we can save a life*

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2. The scientific basis for current US requirements for plasma processing, freezing, and storage has not been clearly established.
3. Harmonization with European requirements is an additional desirable outcome.
4. European requirements are more stringent than US requirements.
5. The scientific basis for current European requirements for plasma processing, freezing, and storage has not been clearly established.
6. To date there has been no demonstrated safety or quality gap in transfusable Plasma or manufactured plasma derivatives between US and Europe.
7. Comments from the user community are focused on safety and availability, and FDA action should reflect these concerns.

Taking these themes into account, ARC offers the following comments for your consideration.

**Red Cross supports the development of rational science-based standards for plasma processing, freezing, and storage.**

**Red Cross supports the development of regulatory standards to allow easier conversion of FFP to plasma for further manufacture.** Red Cross collects FFP concurrently with Platelets, Pheresis. Red Cross' intent for the collection of concurrent FFP is for transfusion. Unexpected events, such as an unexpected Hepatitis B core (HBc) reactive donation or a single storage temperature excursion, may make FFP unacceptable for transfusion but still acceptable for further manufacture.

**In the absence of a clear safety or quality increment, FDA should not add requirements that lack a straight-forward, scientifically supported rationale.** Red Cross supports science-based standards that optimize safety and quality of Plasma and plasma-derived products. Processing, freezing, and storage requirements that exceed the scientific rationale for quality and safety are unnecessary. In the event that scientific data fail to demonstrate the need for more stringent requirements, there should be little or no change to existing requirements.

**FDA should assess the impact to the national blood supply resulting from a change to plasma processing, freezing, or storage requirements.** In comments submitted to Docket 2003N-0211, "Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma; Proposed Rule," Red Cross stated that costs to retrofit for more stringent freezing and storage requirements could reach as high as \$75 – 95 million. FDA should also consider the impact to the nation's blood supply in the event that increased costs associated with more stringent requirements preclude any blood collection organization from continuing to process and manufacture plasma components.

**Red Cross supports harmonization, provided that future harmonization is based upon science-based standards.** World Health Organization requirements for Plasma are currently harmonized with US requirements. Unilateral adoption of European standards

should result only where sound scientific data show that those standards provide the optimum quality and safety conditions. Harmonized standards should reflect multi-lateral negotiation of US, European, and World Health Organization regulators.

The Red Cross appreciates this opportunity to provide these comments on the Workshop and the development of standards for Plasma. If you have any further questions or require follow-up, please contact Richard S. Robinson, at 202-303-5867 (phone), 202-303-0106 (fax) or [RobinsonR@usa.redcross.org](mailto:RobinsonR@usa.redcross.org) (e-mail).

Sincerely,

A handwritten signature in black ink, appearing to read "C. William Cherry". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

C. William Cherry  
Senior Vice President  
Quality & Regulatory Affairs