

April 26, 2004
Reference No. **FDAA04008**

Via E-mail & USPS

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Donor History Questionnaire and Accompanying Materials for Using Screening Human Donors of Blood and Blood Components Draft Guidance." [NOTE: A Docket Number has not yet been assigned to this Draft Guidance issued on April 23, 2004.]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments on the Food and Drug Administration's (FDA) Draft Guidance entitled, "Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Using Screening Human Donors of Blood and Blood Components Draft Guidance." [hereinafter "Draft Guidance"] PPTA notes at the outset that it has not yet reviewed the Draft Guidance in detail, and these submitted comments may be amended or expanded by a later submission.

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

PPTA appreciates the opportunity to submit comments on the Draft Guidance. The Uniform Donor History Questionnaire (DHQ) represents a substantial improvement in donor screening effectiveness and safety. PPTA, along with organizations such as the American Association of Blood Banks, America's Blood Centers, the American Red Cross, and the FDA, has participated as a member of the Interorganizational Task Force responsible for preparation of the DHQ as represented in the Draft Guidance. After preliminary review of the Draft Guidance, we would like to express our enthusiasm

for the enhancement of the donor screening process that the DHQ and accompanying process improvements represent, and our firm belief that it adds measurable levels of improved safety and donor satisfaction.

However, PPTA would also like to express its deep disappointment that it has not yet received official communication (i.e., complete review letter) from the FDA regarding the enhanced DHQ for Source Plasma donors. This project, initiated at FDA's request and submitted to FDA by PPTA on December 10, 2002, has been languishing for over sixteen months. While PPTA is a member of the Interorganizational Task Force, it was decided early in the process that a separate, but similar, DHQ for Source Plasma should be developed to address differences in donor acceptance criteria and donor processing. PPTA member companies have been struggling to update processes, including expensive computer and information systems, with an eye toward following the improved process related to implementation of the DHQ. Unfortunately, FDA has not yet responded in this over sixteen-month time frame, which will entail further delay, expense, and inefficiency when and if the Source Plasma DHQ review is complete.

While we understand that many initiatives of various levels of importance are ongoing, PPTA and its member companies believe that a sixteen-month-plus timeframe for a response to its submission is unacceptable. The DHQ has been given great enthusiasm expressed by members of the Task Force and Blood Product Advisory Committee [hereinafter BPAC], as expressed on p. 5 of the Draft Guidance: "The progress of the task force's activities and the results of the cognitive studies were presented during the BPAC meeting held on June 13, 2002 [reference omitted]. *The BPAC unanimously supported the task force's efforts at each meeting.*" [emphasis added]. PPTA has repeatedly inquired about the status of the Source Plasma DHQ through both formal and informal means and has not received a response.

We look forward to discussing these issues in the near future. Please contact us with any questions you may have. We will continue to review the Draft Guidance in detail and, as mentioned above, may have additional commentary to offer.

Respectfully submitted,



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Plasma Protein Therapeutics Association

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