Plasma Protein Therapeutics Association

Date: July 24, 2007 **VIA WEB & USPS**
Reference No.: FDAA07010

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Guidance entitled, "Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs," June 2007 [Docket No. 2006D–0108]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) wishes to provide comments on the Food and Drug Administration's (FDA) Guidance for Industry "Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs," [hereinafter, "Final Guidance"], dated June 2007. On July 18, 2006, PPTA provided comments on the draft of this guidance document [hereinafter, "Draft Guidance"]. At this time, we request clarification of changes that were made to the Draft Guidance and published in the Final Guidance. 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 is concerned with the change in language in Section II. A. 1. In the Draft Guidance, the language stated, "You must obtain written informed consent from a prospective donor prior to the donor's participation in a Source Plasma donation program." This language is well-understood by the industry and reflects current practice. However, the language was changed to, "Prior to donation, a prospective donor must provide written informed consent." PPTA is concerned that this language may be misinterpreted to require that informed consent be obtained prior to each donation. This is not current practice and has never been the practice of the industry or the expectation of FDA. There is no explanation as to why the language was changed

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nor could we locate comments to the Docket that were helpful in shedding light on the change.

In researching the intent of the informed consent regulation, PPTA found that the preamble to the Final Regulation--July 20, 1973, 21 CFR Part 273, offers only, ". . .the Commissioner has determined that a specific provision should be added to ensure that informed and intelligent consent of each donor is obtained." In practice, the process of obtaining informed consent has been as stated in the Draft Guidance. We request that FDA clarify the Final Guidance to make it clear that informed consent need not be obtained prior to each donation. Otherwise, the Final Guidance may be interpreted as setting a new regulatory requirement.

In addition, we note that the requirement from 21 CFR 640.61 to ". . .include the risks of a hemolytic transfusion reaction if he is given the cells of another donor. . ." was added to Section II. A. 3. b. of the Final Guidance. While the language includes the parenthetical "e.g., when manual plasmapheresis is performed," PPTA requests that you clearly indicate in the Final Guidance that this is not a hazard with automated Source Plasma collection and need not be in informed consents for automated procedures. Again, there was no indication from comments to the Docket why this outdated regulatory language was added to the Final Guidance, but its addition has resulted in questions about its intent.

We appreciate the opportunity to comment on changes to the Draft Guidance that appear in the Final Guidance that may be subject to misinterpretation. Should you have any questions regarding these comments or would like additional information, please contact PPTA.

Respectfully submitted,

Mary Gustafson
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Plasma Protein Therapeutics Association