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VIA E-MAIL & USPS

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

SUBJECT: Draft Guidance entitled, "Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs" [Docket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

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA) Draft Guidance for Industry "Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs," [hereinafter, "Draft Guidance"].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.

We appreciate the opportunity to comment on this Draft Guidance. We note that the recommendations delineated in this Draft Guidance have been the standard used by FDA for some time. Therefore, PPTA would like to take this opportunity to comment on the process for guidance development and its use. PPTA commends FDA for publishing the Draft Guidance, which allows public comment on FDA's current interpretation of federal regulations. PPTA believes it is important for FDA to develop draft guidance documents which help the industry understand the Agency's current thinking. It is critical that FDA publish guidance documents for public and industry comment, rather than new policies being developed on a case-by-case basis. Only through the proper publication of draft guidance documents are PPTA members able to comment on and comprehend Agency policies. Furthermore, it is imperative that FDA

finalize draft guidance documents, which will enable our members to stay compliant with current Agency recommendations.

PPTA appreciates the opportunity to comment on the Draft Guidance. Should you have any questions regarding these comments or would like additional information, please contact PPTA.

Respectfully submitted,



Mary Gustafson
Senior Director, Global Regulatory Policy
Plasma Protein Therapeutics Association