

January 18, 2006
Reference No.: FDAA06001

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

VIA E-Mail & USPS

SUBJECT: Draft Guidance, "Guidance For Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies."
Docket No. 2005-0362

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments on the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Guidance For Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies." [Hereinafter "Draft Guidance Document" or "Guidance"].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PPTA has no specific comments on the content of this Draft Guidance Document. The criteria outlined in the document have been in effect for over a decade and previously were noted in a draft reviewers' guide. However, PPTA wishes to comment on the process for guidance development and its use. PPTA commends FDA for publishing the Draft Guidance Document, which allows public comment on FDA review criteria. PPTA believes it is important for FDA to develop draft guidance documents when considering new biologics license application (BLA) review criteria that are not implicitly delineated in regulations. It is critical that new criteria be published by FDA for public and industry comment, rather than those criteria being imposed on a single manufacturer in the process of reviewing an individual BLA. While PPTA appreciates FDA's willingness to discuss "current thinking" with regard to new criteria in advisory committee meetings and other meetings, it is only through the Good Guidance Practices

process of developing guidance documents that industry and others have the opportunity to provide comments on the Agency's "current thinking."

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