PPTA
Plasma Protein Therapeutics Association

September 23, 2003
Reference No. FDAA03008

VIA E-MAIL and 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SUBJECT: Draft Guidance entitled, "Guidance for Industry: Revised Recommendations for Donor and Product Management Based On Screening Tests for Syphilis"
Docket No. 2003D-0236

Dear Sir or Madam:

PPTA is pleased to provide these comments on the Food and Drug Administration's (FDA's) draft guidance entitled, "Guidance for Industry: Revised Recommendations for Donor and Product Management Based On Screening Tests for Syphilis" (hereinafter "Draft Guidance"). The Plasma Protein Therapeutics Association (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PPTA would like to express its concern regarding the proposed Draft Guidance. Historically, one of the main difficulties in syphilis testing has been the unnecessary deferral of individuals having been successfully treated for syphilis. While the policy iterated in the Draft Guidance will eliminate false positives, it does not address the greater issue of discerning old, treated syphilis infections from active, untreated syphilis infections.

PPTA also has concerns regarding the necessity of continued syphilis screening. The low level of benefits associated with the high costs of continued syphilis screening militates against its continued use. Every year, the plasma collection industry adds new screening tests for new infectious diseases that present a larger profile of danger than syphilis. While syphilis was a historically devastating disease, today, there is little risk associated with it in terms of the plasma industry. PPTA asks that FDA re-open the discussion on elimination of syphilis testing. In light of the economic climate, the

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industry cannot afford to add new tests and continue to retain outdated tests with limited public health value with respect to donor safety and no value in terms of product safety and efficacy.

PPTA appreciates the opportunity to comment on this Draft Guidance.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

Respectfully submitted,

Mary Gustafson

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Plasma Protein Therapeutics Association