

October 25, 2005

Reference No.: FDAA05018

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SUBJECT: Draft Guidance, "Guidance For Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry, July 2005

Docket No. 2005D-0261

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Guidance For Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry." [Hereinafter "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 and its member companies would like to express support for the Agency's updated Guidance Document on NAT for HIV-1 and HCV that includes recommendations not only for testing, but also for product disposition, donor deferral and donor reentry. PPTA has no comments on the content of the Guidance Document. PPTA does offer the suggestion that the Guidance could be more user friendly in terms of organization. PPTA suggests that the document be ordered so that each recommendation includes its narrative recommendation and respective figures and tables. Perhaps this could be done by organizing the individual recommendations in a series of appendices.

PPTA appreciates the opportunity to comment on the Draft Guidance.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