

**PPTA Statement on Management of Donors and Units that Test Positive for Hepatitis B Virus (HBV) DNA by Nucleic Acid Tests (NAT)**

**FDA Blood Products Advisory Committee  
July 21, 2005**

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments to the Blood Products Advisory Committee (BPAC) on the issue of management of donors and units that test positive for Hepatitis B Virus (HBV) DNA by Nucleic Acid Tests (NAT).

PPTA agrees with FDA's efforts to provide a means to resolve false positive HBV NAT results in blood and plasma donors and to develop algorithms that allow donor reentry. PPTA further encourages FDA to provide guidance for resolving false positive results for all required and recommended tests for appropriate donor notification and to develop a comprehensive donor reentry schema that incorporates NAT testing, with relevant and scientifically determined intervals for reentry testing. PPTA notes that FDA has just released a draft guidance entitled, "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product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." PPTA has not yet reviewed the document in detail and will comment at a later date but hopes that the guidance provides the necessary steps for resolution of false positives and donor reentry.

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.