

May 23, 2005

Reference No.: FDAA05010

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**SUBJECT:** Draft Guidance, "Guidance For Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection", April 2005

**Docket No. 2005D-0133**

And Direct Final Guidance, "Discontinuation of Donor Deferral Related to Recent Fever With Headache as a Symptom of West Nile Virus Infection", May 2005

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these additional comments on the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Guidance For Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection." [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 West Nile Virus, in conjunction with the Direct Final Guidance document, "Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection." We agree with the Agency that the non-specific question for self-reporting of fever with headache did not elicit information that would bear relevance to a West Nile Virus infection and appreciate the Agency's willingness to remove a recommendation that is found not to add value to the safety of blood products. We also agree with the FDA's announced policy of removal of

this question via a collection center's submittal of an annual report under 21 CFR §601.12(d).

In the Draft Guidance Document, there are areas for potential confusion with respect to the need for testing prior to re-entering donors. It would be helpful if the Agency would clearly state that "re-testing" is not recommended unless the facility re-entering the donor is in possession of the original positive test result. Making that distinction would clarify that a test is not necessary if a donor reports that he had a clinical case of West Nile Virus fever, with or without testing at a doctor's office or other facility

Respectfully submitted,



Mary Gustafson  
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Plasma Protein Therapeutics Association