

May 19, 2008  
Reference: FDAA08011

**VIA WEB & USPS**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, RM 1061  
Rockville, MD 20857

**SUBJECT: Docket No. FDA-2008-N-0121, Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information**

Dear Sir or Madame:

The Plasma Protein Therapeutics Association (PPTA) is pleased to respond to the Food and Drug Administration's (FDA) Request for Information, *Technologies for Prescription Drug identification, Validation, Track and Trace, or Authentication* [hereinafter, "Request for Information"]. 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 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.

While PPTA cannot speak directly to the questions posed in the Federal Register published on March 20, 2008, (Vol. 73, No. 55), PPTA would like to provide some general comments. As FDA considers the development of standards for a standardized numerical identifier, validation, track and trace, and authentication of prescription drugs, the Agency needs to allow for flexibility in the adoption of accompanying technologies. As PPTA has stated in previous comments to dockets FDA- 2003N-036, FDA-2005N-0510, and FDA-2008-N-0120, manufacturers know their products and business practices best and are in the best position to determine the correct anti-counterfeit technologies to implement. Any guidance developed by FDA must recognize this and allow for flexibility in implementation. Some carrier technologies do not work properly or may have detrimental effects on biologics. For example, the effect of RFID on biologics is still unknown. PPTA understands FDA completed a study regarding the effects of RFID on biologics. However, this study remains unpublished. PPTA recommends FDA make this study publicly available to allow industry the opportunity to review and

evaluate RFID appropriately. PPTA reiterates the need for the Agency to remain flexible as they move forward with this initiative.

PPTA members are committed to eliminating the counterfeit drug problem in the U.S. and globally. PPTA appreciates the opportunity to provide information to the Agency on this important topic and looks forward to working with FDA on developing a solution.

Sincerely,



Mary Gustafson  
Vice President, Global Regulatory Policy  
Plasma Protein Therapeutics Association