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VIA WEB & USPS

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: *Federal Register Notice: Participation of Certain Population Subsets in Clinical Drug Trials; Request for Comment [Docket No. FDA-2009-N-0674]*

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) *Request for Comment—Participation of Certain Population Subsets in Clinical Drug Trials*. 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 appreciates the opportunity to provide comments on issues related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA) Section 901, which requires recommendations be included in a report to Congress addressing best practice approaches on increasing the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical trials. In response to the request, PPTA wishes to express its concern that a strict interpretation of statutory language on clinical trial enrollment would have a chilling effect on the development drugs intended to treat rare diseases, which are manufactured by PPTA member companies. We trust that in developing implementing regulations and policies, FDA will carefully consider the implications and impediments to enrolling the various subsets of the population in clinical trials for drugs that are life-sustaining for a small but vulnerable population.

If you have any questions, please contact me at the Association.

Respectfully submitted,



Vice President, Global Regulatory Policy
Plasma Protein Therapeutics Association