PPTA
Plasma Protein Therapeutics Association

February 6, 2004
Reference No. FDAA04004

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

VIA E-Mail & USPS

SUBJECT: Proposal, "Amending the MedWatch Forms to Collect Postmarketing Adverse Events Data Relating to Race and Ethnicity."
Docket No. 2003N-0529

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA's) Proposal entitled, "Amending the MedWatch Forms to Collect Postmarketing Adverse Events Data Relating to Race and Ethnicity" [hereinafter "Proposal"]. 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 is of the opinion that changes to the adverse events data collection system will result in costs to industry. Revision of the forms themselves will also entail revision and modification to the adverse event management software. These costs are not likely to be offset by a benefit to FDA in data collection capability. Many reasons exist for this, but perhaps the largest concern is a reluctance of health care providers to provide such information, due to the chilling effect that the Privacy Rule (45 CFR Parts 160 and 164 [Subparts A and E]) under the Health Insurance Portability and Accountability Act (HIPAA) may have. Fear of investigation, administrative sanction, and avoidance of these costs is something that is just beginning to be investigated by a number of interested groups, both governmental and non-governmental.

Respectfully Submitted,

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