PPTA
Plasma Protein Therapeutics Association

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

VIA E-Mail & USPS

SUBJECT: Draft Guidance for Industry, "INDs—Approaches to Complying with CGMP During Phase 1"
Docket No.: 2005N-0285

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA) Draft Guidance for Industry "INDs—Approaches to Complying with CGMP During Phase 1" [hereinafter, "Draft Guidance Document" or "Draft Guidance"].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.

We appreciate the opportunity to comment on this Draft Guidance Document and commend the Agency for revising cGMP regulations to exempt Phase 1 studies from the requirements. PPTA has the following comments regarding the Draft Guidance Document.

- It is not uncommon for our member companies to utilize a combined Phase 1/2 study plan. It would be helpful if the Document addressed this scenario. In addition, while the definitions of Phase 1, Phase 2, and Phase 3 studies are included in Title 21, Code of Federal Regulations, Part 312.21, it would assist sponsors reading this Document if those definitions and definitions for Phase 1/2 and Phase 2/3 were included in the Glossary of this Document.

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- In item II. Background, you discuss a limitation of the 1991 "Guideline on the Preparation of Investigational New Drug Products (Human and Animal)," as ". . .the 1991 document did not address fully the Agency's expectation that an ***incremental approach*** to manufacturing controls would be taken during investigational drug development. . ." However, the Draft Guidance Document offers only a two tiered approach, i.e., expectations for Phase 1 and full cGMP requirements for other phases of study. If the Agency truly expects an ***incremental approach*** throughout the study phases, this should be mentioned and covered in a subsequent Guidance Document.

PPTA appreciates the opportunity to comment on the Draft Guidance. Should you have any questions regarding these comments or would like additional information, please contact PPTA.

Respectfully submitted,

Mary Gustafson
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Plasma Protein Therapeutics Association