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Reference No.: FDAA07017

VIA WEB

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

SUBJECT: Direct Final Rule/Proposed Rule: Revisions to the Requirements
Applicable to Blood, Blood Components and Source Plasma [Docket No.
2007N-0264]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA) Direct Final Rule/Proposed Rule: Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma [hereinafter, "DFR"]. 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 comment on this DFR. PPTA agrees with FDA's decision to publish the DFR in its continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations. PPTA has no significant adverse comments on the DFR insofar as the changes are meant to revise outdated regulations to reflect current practices. In some areas of the requirements applicable to blood, blood components and source plasma, PPTA views further revision advisable. Specifically, FDA proposes an alternative definition of Plasma at 21 CFR 640.30(a). PPTA recommends that the proposed definition at 21 CFR 640.30(a)(2) be further amended to include "for intravenous or further manufacturing use."

The additional revision in definition will facilitate use of plasma for manufacturing use that has been collected concurrently with the collection of another blood component by apheresis. Such plasma is collected in accordance with the donor suitability

requirements in 21 CFR 640.3 if collected on an infrequent basis. "Infrequent" has been defined in recommendations by FDA as no more than once in four weeks. When collected infrequently, concurrent plasma should not be called Source Plasma and there need not be additional requirements for medical supervision, initial and annual physical examinations, protein tests at each donation or periodically. A suitably appropriate name, such as Component Plasma, should be given to the component and requirements for processing added to 21 CFR 640.34. Other provisions in the regulations between Plasma for transfusion and Component Plasma for further manufacturing use should be harmonized as much as possible to allow interchangeability of the plasma from intravenous use to manufacturing use at anytime after collection.

PPTA appreciates the opportunity to comment on the DFR. 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