PPTA
Plasma Protein Therapeutics Association

June 10, 2003
Reference No. FDAA03006

2921 '03 JUN 11 A9:24

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

SUBJECT: Proposed Rule: Bar Code Label Requirement For Human Drug Products and Blood
Docket No. 02N-0204

Dear Sir or Madam:

PPTA is pleased to provide these comments on the Food and Drug Administration's (FDA's) proposed rule entitled, "Bar Code Label Requirement for Human Drug Products and Blood." The Plasma Protein Therapeutics Association (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, and burns among other things. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies for the people who depend on them.

PPTA member companies support the use of automated technology in labeling human drug and blood products. However, the proposed rule limits the technology to linear bar coding. PPTA is concerned that such language in a regulation may inhibit advances in labeling technology. PPTA recommends that the regulation address the standard, not the technology. Specific technologies could be described in a guidance document that is more easily revised as technology advances. ISBT 128 is an example of a standard that has specific data identifiers that are independent of technology.

PPTA members companies supply Source Plasma used in the manufacture of plasma derived therapies. It is our understanding that Source Plasma, as a blood component but not a final dosage product, is not included within the scope of this proposed rule.

PPTA appreciates the opportunity to comment on this Proposed Rule. Should you have any questions regarding these comments or would like additional information, please contact PPTA. Thank you for your consideration.

Respectfully submitted,

Mary Gustafson
Senior Director
Global Regulatory Policy

cc: Julie Birkofer, PPTA
PPTA Regulatory Policy and Compliance Steering Committee

02N-0204 C63

Mailing Address: 147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
Washington Office: Washington Harbour · Suite 400 · 3050 K Street NW · Washington, DC 20007 USA
Brussels Office: Boulevard Brand Whitlock 114/5 · 1200 Brussels · BELGIUM
tel: 202.789.3100 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.plasmatherapeutics.org