Plasma Protein Therapeutics Association

Date: September 7, 2018

Submitted Electronically
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

SUBJECT: Docket No. FDA–2018-D-1895 for "Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry"

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) thanks FDA for the opportunity to participate in the guidance development process and is pleased to provide these comments on the draft guidance for industry and FDA staff, "Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format" dated July 2018 (hereinafter, "Draft Guidance").

About PPTA

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies, collectively referred to as plasma protein therapies. Plasma protein therapies are used mostly in the treatment of several rare diseases. These diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. These therapies include clotting therapies for individuals with bleeding disorders, immunoglobulins (IG) to treat a complex of diseases in persons with severe autoimmune 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 to treat individuals with severe liver diseases and, in emergency-room settings, shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

PPTA Comments

Section II.A.1.

The guidance discusses having an age range in the indication. This is potentially based upon the age of the population studied and also the opinion of the FDA reviewers as regards safety outside this range. While clearly indicating the age range for the pediatric group is wise, for the adult population specifying an age range in the indication has the issue that there is now a limitation of the availability of the medicine to a population that could have a favorable benefit-risk. Alternatively, generalizing to "adults" may provide

insufficient information about a subset, e.g. geriatric patients, for whom there may be limited data and for whom the drug may be metabolized differently. It appears that there may be insufficient guidance for the geriatric subset. This seems to be an omission as this is an increasing population in the real world and has the highest levels of morbidity requiring drug therapy.

Conclusion

PPTA appreciates the opportunity to provide comments concerning the draft guidance intended to assist applicants in drafting the INDICATIONS AND USAGE section of labeling as described in the regulations for the content and format of labeling for human prescription drugs and biological products. PPTA welcomes any questions or comments regarding our response. Thank you for your consideration.

Respectfully submitted,

Mary Gustafson
Vice President, Global Regulatory Policy
Plasma Protein Therapeutics Association