Plasma Protein Therapeutics Association

Date: June 3, 2016
Reference No.: FDAA16008 VIA EMAIL

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

SUBJECT: **Comments to Docket No. FDA-2016-D-0643**, "Guidance for Industry: Labeling for Biosimilar Products"

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for the opportunity to participate in the guidance development process and is pleased to provide these comments on the draft guidance for industry "Labeling for Biosimilar Products" dated March 2016 (hereinafter "Draft Guidance").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 a number of 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 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.

General Comments

PPTA understands that the scope of the Draft Guidance is limited to recommendations for ". . . prescribing information (commonly referred to as the package insert), except for recommendations in section V pertaining to FDA-approved patient labeling. . ." and does not cover interchangeable biological products. PPTA notes that 81 FR 19194 specifically invites comments on ". . .whether patient labeling. . .should include a biosimilarity statement similar to the statement described in section IV.C.1 of the draft guidance."

Specific comments on the Draft Guidance follow:

Section III. General Principles for Draft Labeling of Proposed Biosimilar Products (Biosimilar Product Labeling)

CLINICAL DATA – Keeping in mind that the purpose of the prescribing information is to provide only the information that will allow the prescriber to use the product safely and effectively, we support FDA's view that the presentation of clinical data in the biosimilar product label generally should be restricted to those clinical data generated with the reference product. Clinical data generated with the proposed biosimilar are to demonstrate biosimilarity, not to re-establish safety and efficacy, and therefore will not be relevant for health care providers in the context of prescribing. However, we recommend that FDA permit the inclusion in labeling of certain types of clinical data generated with the proposed biosimilar, when the data will be of specific interest and utility to health care providers. For example, with regard to safety/immunogenicity data for transitioning from the reference product to the biosimilar and/or from the biosimilar to the reference product, even though transition studies are not required for approval of a biosimilar, many sponsors will conduct them and they are important for prescribers and treatment decisions. The inclusion of such data for transition between products should be only for the reference product and the applicant's biosimilar, not for transitions between biosimilar products.

Section IV. Specific Recommendations on Content of Biosimilar Product Labeling, item C.1.

PRODUCT IS A BIOSIMILAR – The Draft Guidance recommends that biosimilar products be identified as such on the labeling and that the reference product be named (e.g., "x product is a biosimilar to y reference product "). We are not aware of a scientific or clinical reason for including the term "biosimilar" on the label. The proposed labeling statement appears to imply that knowing a product is a biosimilar is important, presumably in order to differentiate between the biosimilar product and the reference product. However, we do not agree that this is relevant information to allow the safe and effective use of the product, since all biosimilar products are approved as having no meaningful clinical differences from their reference product. Making such a distinction creates an impression that biosimilar products are different from, and potentially inferior to, the reference product—clearly something FDA does not intend to convey. Inclusion of such a statement could create doubt and hamper acceptance and adoption by prescribers and patients. Further, this proposal represents a change in policy from what was required in the Zarxio™ labeling, where such a statement was not required, and which FDA defended. We recognize that FDA may have non-scientific considerations for this proposal; it would be helpful to better understand FDA's rationale for its proposal. While the non-scientific issues may be considerable and have merit, our concern remains that creating this distinction in labeling could have the opposite effect and act to decrease acceptance and uptake of biosimilar products. Therefore, we do not believe the proposed statement is necessary for the safe use of the product and do not support this recommended labeling statement in prescribing information nor its inclusion in patient labeling.

Conclusion

PPTA appreciates the opportunity to comment on the Draft Guidance and looks forward to continued work with FDA on its recommendations for biosimilar products. PPTA welcomes from FDA any questions regarding these comments.

Thank you for your consideration.

Respectfully submitted,

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