Plasma Protein Therapeutics Association

June 7, 2011
Reference No.: FDAA11011

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

SUBJECT: Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for FYs 2013-2017 [Docket No. FDA-2011-N-0326]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on Options for a User Fee Program for Biosimilar and Interchangeable Product Applications for FYs 2013-2017.[1] PPTA strongly supports the Food and Drug Administration (FDA) in its efforts "to develop proposed recommendations for a user fee program for 351(k) applications for fiscal years (FYs) 2013 through 2017."[2] PPTA is the international trade association and standards-setting organization for the world's major collectors of Source Plasma and manufacturers of plasma derived products and recombinant analogues, collectively referred to as plasma protein therapies. The therapies are used in the treatment of a number of rare diseases. The diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of the therapies for the duration of their lives. The therapies include clotting-factor therapies for individuals with hemophilia A and B and other bleeding disorders; immunoglobulins to treat a complex of diseases in individuals with immune deficiencies; therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset emphysema and limits substantially life expectancy; and albumin, which is used in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions. Members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

PPTA agrees with FDA's principles for developing the user fee program and the Agency's proposals; namely, that the program should be funded comparably to the current PDUFA fees for licensed biologicals, except that part of the application fee would be assessed early in the biosimilar and interchangeable product development cycle as a biosimilar product development fee. In particular, PPTA supports FDA's proposed fee structure, which is similar to PDUFA for at least the first five years because reviews are "expected to be comparably complex, technically demanding, and

[1] Federal Register / Vol. 76, No. 90 / Tuesday, May 10, 2011 / Notices, pp. 27062-7
[2] Id. at 27062

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resource-intensive as review of a proposed 351(a) application"[3] and front loaded "to support activities that occur early in the biosimilar and interchangeable product development cycle"[4] taking into account that the program is new and most of the Agency's activities to date have been "focused on development of regulatory standards, policy, and consultations with 351(k) sponsors."[5] PPTA agrees with FDA that it is essential to front load the fee structure to "ensure adequate resources for the review of 351(k) user fee applications, so that critical resources for 351(a) review are not redirected from innovator drug review to biosimilar products."[6] PPTA also supports FDA's performance goals that extend from reviewing and acting on 50% of applications within 10 months in 2013 to 90% of applications within 10 months in 2017.

PPTA appreciates the opportunity to comment on Options for a User Fee Program for Biosimilar and Interchangeable Product Applications for FYs 2013-2017 and looks forward to continued work with FDA on its efforts to develop proposed recommendations for a user fee program for 351(k) applications for FYs 2013-2017. PPTA welcomes from FDA any questions regarding these comments and/or requests for additional information.

Thank you for your consideration.

Respectfully Submitted,

Mary Gustafson
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Plasma Protein Therapeutics Association

[3] Id. at 27063
[4] Id.
[5] Id.
[6] Id.