Plasma Protein Therapeutics Association

Date: March 27, 2017
Reference No.: FDAA17005 VIA EMAIL

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

SUBJECT: Submission of Quality Metrics Data; Draft Guidance for Industry; Availability; Request for Comments [Docket No. FDA–2015–D–2537]

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to participate in the guidance development process and is pleased to provide these comments on the Agency's revised draft guidance entitled "Submission of Quality Metrics Data" ("Revised Draft Guidance").[1] PPTA understands that the Revised Draft Guidance replaces the Agency's draft guidance entitled "Request for Quality Metrics" ("Draft Guidance"),[2] on which the Association commented on November 25, 2015. As an industry association, PPTA can discuss issues of interest to the Association and FDA at an annual liaison meeting held primarily with representatives from the Center for Biologics Evaluation and Research (CBER). PPTA appreciates CBER's participation at the liaison meetings on September 16, 2015, in Bethesda, Maryland, and on September 28, 2016, in Rockville, Maryland, and the dialogue provided regarding this subject. PPTA understands that the Revised Draft Guidance includes the following changes from the Draft Guidance:

> Adoption of a phased-in (voluntary) approach, reduction in the number of data elements requested (i.e., reduction in reporting burden), support for both product reports and site reports, modifications to the quality metrics data definitions, addition of clarifying examples for the definitions, addition of comment fields, and clarification of special considerations for non-application and OTC product reporting.[3]

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 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

[1] http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm455957.pdf accessed Jan. 6, 2017
[2] *See* FR Notice, 80 Fed. Reg. 44973 (Jul. 28, 2015)
[3] *See* FR Notice, 81 Fed. Reg. 85226, 85228 (Nov. 25, 2016)

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 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.

Scope of Revised Draft Guidance

Source Plasma

PPTA understands that, with certain exceptions, "owners and operators of each establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a covered drug product, or an API [active pharmaceutical ingredient] used in the manufacture of a covered drug product, may submit quality metrics data."[4] PPTA considers Source Plasma, which Association members collect, a raw material used in the production of plasma protein therapies. PPTA would like to confirm that FDA also considers Source Plasma a raw material, and not an API.

Human Plasma-Derived Therapeutics

PPTA was concerned by the fact that human plasma-derived therapeutics were specifically excluded from the Draft Guidance.[5] At the September 2015 liaison meeting and in PPTA's November 2015 comment letter, the Association requested that FDA consider removal of this exclusion. In particular, the exclusion unjustly implied to PPTA, patient communities, and healthcare providers that the quality systems established by member companies were not capable of being, or are not currently, in compliance with existing regulatory expectations. In addition, in the absence of removal of the exclusion, member companies, while being expected to comply with all applicable CFR requirements, would essentially be penalized by not being able to benefit from reduction in inspection frequency or changes in regulatory filing categorization. Further, PPTA fully expected that, despite being excluded from the scope of the Draft Guidance, FDA inspectors would continue to request this information while performing on-site inspections. Lastly, the Draft Guidance would have served to create inefficiencies at establishments that manufacture products that were both included in the scope of the Draft Guidance and those that were excluded from the Draft Guidance. Accordingly, PPTA appreciates that FDA adopted the Association's recommendation to remove the language which excluded human plasma-derived therapeutics from the scope of the guidance.[6]

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[4] *See* Revised Draft Guidance at 5
[5] *See* Draft Guidance at 2 & 10
[6] *See* Revised Draft Guidance at 2

Conclusion

PPTA appreciates the opportunity to comment on the Revised Draft Guidance and looks forward to continued work with FDA on Quality Metrics. PPTA welcomes from FDA any questions regarding these comments.

Respectfully submitted,

Mary Gustafson
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Plasma Protein Therapeutics Association