Plasma Protein Therapeutics Association

Date: March 2, 2016
Reference No.: FDAA16002 **VIA EMAIL**

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

SUBJECT: Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry; Availability
Docket No. FDA-2014-D-2175

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for the opportunity to participate in the guidance development process and is pleased to provide these comments on the draft guidance for industry "Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus" dated December 2015 (hereinafter "Draft Guidance").[1]

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PPTA understands that the Draft Guidance provides establishments that routinely collect blood and blood components for transfusion or further manufacture, including

[1] Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus. FDA. Dec. 2015. http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM475072.pdf accessed Feb. 8, 2016.

Source Plasma, with recommendations for assessing donor suitability, donor deferral, and product management in the event that an outbreak of Ebola virus disease (EVD) with widespread transmission is declared in at least one country.[2] PPTA recognizes that the recent outbreak of EVD has caused great concern worldwide, including concern by FDA that blood and blood products from symptomatic individuals, if they were to donate, would have the potential of transmitting EVD to recipients.[3] PPTA also recognizes that people who rely on plasma protein therapies may have concerns about the safety of these therapies, e.g., clotting factors, immune globulins, alpha-1 proteinase inhibitor, and albumin.

PPTA members are committed to providing safe and effective therapies and have responded effectively and rapidly to the EVD outbreak. Since October 13, 2014, PPTA members collecting Source Plasma have been voluntarily following the 60-day deferral recommendation from the European Centre for Disease Prevention and Control.[4] The same day, PPTA posted a statement, "Ebola Virus and Plasma Protein Therapies," on its website.[5] However, PPTA does not believe that the amount of effort that will be expended in implementing the extensive recommendations contained in the Draft Guidance match the risk that EVD presents to plasma protein therapies.[6] PPTA recommends that compliance with relevant FDA recommendations be allowed via Source Plasma centers' donor educational material, which are a part of each center's standard operating procedures and discussed further later in this letter, and donor self deferral.

PPTA also notes that the Draft Guidance points to U.S. Centers for Disease Control and Prevention (CDC) web pages that were created for purposes other than Source Plasma collection, change frequently, and do not contain all the information needed to implement FDA's recommendations or highlight updated information corresponding to Alert Notices. PPTA recommends that FDA and CDC's Office of Blood, Organs and Other Tissue Safety collaborate with industry to ensure that the necessary information is available to assess whether Source Plasma donors are in compliance with FDA's recommendations.

Specific comments on the Draft Guidance follow:

Applicability

Section I of the Draft Guidance, "Introduction," states that "[t]his guidance document applies primarily to Ebola virus (species *Zaire ebolavirus*), but recommendations are

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[2] *See* FR Notice, 80 Fed. Reg. 75681 (Dec. 3, 2015).
[3] *See* Draft Guidance at 2.
[4] The risk of transmission of Ebola virus via donated blood and other substances of human origin in the EU. ECDC PHE technical document. 6 Oct. 2014. http://www.ecdc.europa.eu/en/publications/Publications/ebola-risk-transmission-via-donated-blood-substances-human-origin-october-2014.pdf accessed Feb. 29, 2016.
[5] http://www.pptaglobal.org/media-and-information/ppta-statements/922-ebola-virus-and-plasma-protein-therapies accessed Feb. 29, 2016.
[6] *See id.*

expected to apply to other viruses of the Ebolavirus genus such as Sudan virus, Bundibugyo virus, and Tai Forest virus."

The statement is the only reference to the other viruses of the EVD genus that appears in the Draft Guidance. FDA's recommendations/expectations for questioning donors about these other viruses is unclear. Clarification is needed, as all of the recommendations in the remainder of the Draft Guidance refer only to EVD.

Donor educational material

Section III of the Draft Guidance, "Recommendations," states that "[t]he guidance contains recommendation for updating your donor educational materials in section III.A.1."[7] Section III.A.1. states that *"[y]ou may* update your donor educational materials to instruct donors with a *history of Ebola virus infection or disease* to not donate blood or blood components."[8]

PPTA would appreciate clarification on the expectations for the donor educational material. First of all, the phrase "[y]ou may" in Section III.A.1. is unclear. Is FDA recommending that companies update their educational materials or not? The inconsistent use of the language (may v. recommend) is confusing. Clarification is requested.

Secondly, if and when companies do update their educational materials, is a statement such as "You should not donate if you have a history of Ebola virus infection or disease" sufficient? If not, PPTA notes that the CDC website does provide some detail on the risks, but it is not clear on what risk factors companies should focus their attention.

Conclusion

PPTA appreciates the opportunity to comment on the Draft Guidance and looks forward to continued work with FDA on its recommendations for assessment of blood donor suitability, donor deferral and product management in response to EVD. PPTA welcomes from FDA any questions regarding these comments.

Thank you for your consideration.

Respectfully submitted,

Mary Gustafson
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[7] *See* Draft Guidance at 3.
[8] *See id.* (emphases added).