Plasma Protein Therapeutics Association

September 1, 2011
Reference No.: FDAA11017

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

SUBJECT: International Conference on Harmonisation (ICH); Draft Guidance on Q11 Development and Manufacture of Drug Substances (Q11); Availability [Docket No. FDA-2011-D-0057]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (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, which 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 plasma protein 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. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

PPTA welcomes the opportunity to discuss plasma protein therapies via written submissions. PPTA thanks FDA for the opportunity to participate in the guidance process and is pleased to provide these written comments on Q11, which was prepared under the auspices of the ICH of Technical Requirements for Registration of Pharmaceuticals for Human Use.[1] PPTA appreciates FDA's efforts to harmonize the scientific and technical principles relating to the description and justification of the development and manufacturing process of drug substances (both chemical entities and biotechnological/biological entities) to enable a consistent approach for providing and evaluating this information across the EU, Japan, and the US.[2]

[1] *See* Federal Register / Vol. 76, No. 125 / Wednesday, June 29, 2011 / Notices, pp. 38187-88
[2] *See id.* at 38187

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Introduction

Q11 describes approaches to developing process and drug substance understanding and provides guidance on what information should be provided in certain sections of the Common Technical Document (CTD).[3] Q11 is an extension of the Guidance for Industry, Q8 Pharmaceutical Development (Q8), which was finalized in the US at the end of 2009. Similar to Q8, which focuses on the drug product Quality Target Product Profile, Critical Quality Attributes, design space, and control strategy included in 3.2.P.2 of the Chemistry, Manufacturing, and Control section of the CTD, Q11 provides guidance on process development incorporating the Quality by Design approach for drug substances in section 3.2.S.2.

General comment

The Introduction to Q11 describes different approaches—"enhanced" as described in the document and "traditional"—in terms of applicability and implementation of the document. While the "enhanced" approach is attractive for new products, its application to marketed products would be difficult or impossible. PPTA suggests that the flexibility of Q11 and expectations for its use in marketed products be clarified, perhaps in a Questions and Answers (Q&A) document. Our industry has found that the May 2010 Guidance for Industry, Q8, Q9, and Q10 Q&A, to be most useful and would suggest a similar approach for clarifying applicability and expectations regarding Q11.

Conclusion

PPTA appreciates the opportunity to comment on Q11 and looks forward to continued work with FDA on its efforts to harmonize the scientific and technical principles relating to the description and justification of the development and manufacturing process of drug substances to enable a consistent approach for providing and evaluating this information across the EU, Japan, and the US. 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.*