Plasma Protein Therapeutics Association

Date: November 14, 2016
Reference No.: FDAA16015 **VIA WEB**

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

SUBJECT: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments; **Docket No. FDA-2016-N-2673**

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) thanks FDA for the opportunity to provide comments regarding the efforts underway to implement the Drug Supply Chain Security Act's (DSCSA's) product identification requirements, including the use of product identifiers to enhance tracing at the product level.[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 several 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 appreciates that FDA held a public meeting on October 14, 2016, to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share information about current practices and industry efforts to implement DSCSA's product identification requirements, including the use of product identifiers.[2] While PPTA did not present at the meeting, the Association has collected the below comments, including questions, for FDA.

Specific comments

1. November 27, 2017, is the date from which manufacturers must start serializing product and passing that data over to third-party logistics providers (3PLs) or distributors.

[1] *See* FR Notice, 81 Fed. Reg. 64175 (Sep. 19, 2016).
[2] *See id.* at 64176.

Subsequent go-live dates for 2018, 2019, and 2020 are for different players in the pharmaceutical supply chain to implement solutions that allow for the serialized data to be exchanged; these are the repackagers, distributors, and wholesalers.

a. During the public meeting on October 14, 2016, FDA gave a slight indication that the Agency wanted to gauge industry readiness. There is an increased concern that the entire industry will not be ready by November 27, 2017. Given the varying degrees of preparation, has FDA considered enforcement options for companies who are unable to meet the November 27, 2017, serialization deadline?

b. It also is not clear how non-serialized inventory in the supply chain on November 27, 2017, should be treated. PPTA encourages FDA to publish draft and then final guidance on grandfathering product as soon as possible. PPTA asks that FDA address, in the guidance, volume and management of non-serialized inventory in the supply chain. Can this inventory be depleted by attrition until the expiration date or will there be an expectation to repackage this? If repackaging is required, should repacking sites in the U.S. be qualified if they are not registered?

c. PPTA also encourages FDA to publish other outstanding DSCSA implementation guidance documents, including those for exceptions, exemptions, and waivers.

2. Serialization will require potential layout changes as well as the addition of serialization. Please confirm that both the addition of serialization and possible layout changes fall within the context of 21 CFR 601.12(f)(3) - Labeling changes requiring submission in an annual report.

3. There are several exceptions to which products will not require to be serialized. This likely is because of assessing the risk of counterfeiting and patient impact. Can serialization requirements be waived for orphan drugs?

Conclusion

PPTA appreciates the opportunity to provide comments regarding the efforts underway to implement DSCSA's product identification requirements, including the use of product identifiers to enhance tracing at the product level. PPTA welcomes from FDA any questions regarding these comments. Thank you for your consideration.

Respectfully submitted,

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Plasma Protein Therapeutics Association