

Date: May 7, 2019

VIA EMAIL

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

SUBJECT: PPTA comments to Docket No. FDA-2019-D-0078; “Principles of Premarket Pathways for Combination Products; Draft Guidance for Industry”

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opportunity to participate in the guidance development process and is pleased to provide these comments on the Agency’s draft guidance entitled “Principles of Premarket Pathways for Combination Products” (“Draft Guidance”).¹ Additionally, the Federal Register notice announcing the availability of the Draft Guidance² asked for input on two issues: 1) . . . those circumstances when a single application may not be appropriate, and thus two applications—one to the lead center and one to the non-lead center—should be submitted; and 2) In those circumstances, are there steps FDA should take to avoid duplication of effort or duplicate data submission and to minimize unnecessary burden?

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. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining 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 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 to treat individuals with severe liver diseases and in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions.

¹<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-premarket-pathways-combination-products>, accessed May 1, 2019

² FR Notice, Fed. Reg. 84 2236 (Feb 6, 2019)

Comments:

PPTA's comments pertain to the request for public comment contained in the Federal Register Notice referenced above:

- 1) . . . *those circumstances when a single application may not be appropriate, and thus two applications—one to the lead center and one to the non-lead center—should be submitted.*
 - a. When companies that own/manufacture device and drug constituent parts of a combination product are different, and therefore, want to restrict access to proprietary information.
 - b. When one company is the manufacturer of a drug and/or device that is part of a combination product but chooses to remain the manufacturer of that drug and/or device independent from the combination product.
 - c. When one constituent part of the combination product (drug or device) is also used in multiple combination products. In this case, it may be more practical for the manufacturer of that part to file a single submission containing information that can be used in multiple combination products submissions.

- 2) *In those circumstances, are there steps FDA should take to avoid duplication of effort or duplicate data submission and to minimize unnecessary burden?*

Please consider the following suggestions for filings:

- a. For drug-device and biologic-device submissions (drug/biologic led submissions), create a new quality module that mirrors a device 510(k) submission that can be incorporated into an NDA or BLA where all the device verification and validation can be included. Currently, all the device information is included in Module 3, section 3.2. Regional, which typically has other attachments that relate to the drug portion of the filing like executed batch records and reports.

- b. For device led submissions, create a quality module/section that mirrors the CMC section of a drug submission, in which all the drug quality information can be submitted under a 510(k) or Pre Market Approval.

- c. Add a section in which filings can reference the Global UDI Database (GUDID) information for all devices to facilitate UDI requirements, if applicable.

- d. Add a section in which an electronic Device Master Record (DMR) could be accessed, permissible either by a link or portal and/or device CDRH registration database.

Conclusion

PPTA appreciates the opportunity to comment on the Draft Guidance. PPTA welcomes from FDA any questions regarding these comments.

Respectfully submitted,



Mary Gustafson
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Plasma Protein Therapeutics Association