Plasma Protein Therapeutics Association

Date: May 31, 2016
Reference No.: FDAA16007 VIA EMAIL

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

SUBJECT: **Comments to Docket No. FDA-2016-N-0406**, "Proposed rule; Medical Devices; Hematology, Blood Establishment Computer Software and Accessories," 81 FR 10553

Dear Sir or Madam:

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.

The Plasma Protein Therapeutics Association (PPTA) thanks FDA for the opportunity to participate in notice and comment rulemaking and respectfully submits comments to the referenced FR notice.

PPTA agrees with FDA's proposed classification of Blood Establishment Computer Software (BECS) and BECS accessories into Class II (special controls) with the continued requirement for premarket notification [510(k) clearance]. Additionally, we agree that the "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 2005, includes the risk mitigations proposed for "special controls."

PPTA asks for clarification of the identification and definition of BECS accessories. The wording in proposed 21 CFR 864.9165(a), is not sufficiently precise with respect to BECS accessories, i.e., "A BECS accessory is intended for use with BECS to augment its performance or to expand or modify its indications for use." We are concerned that this wording could be interpreted to include a variety of applications or interfaces that, in

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fact, do not “augment” BECS performance or “expand or modify its indications for use.” An interfaced “data pass through” system without data manipulation should not “expand or modify its indications for use”, and should not require a 510(k). For clarity, it is important for FDA to provide examples so that applications and interfaces, including Medical Device Data Systems (MDDS) or utilities, which do not present the risk associated with a Class II device are not mis-identified as “BECS accessories.”

PPTA appreciates the opportunity to comment on this proposed rule and welcomes from FDA any questions regarding these comments.

Thank you for your consideration.

Respectfully submitted,

Mary Gustafson
Vice President, Global Medical and Regulatory Policy
Plasma Protein Therapeutics Association