America's Blood Centers®
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April 24, 2023

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

Re: **Docket No. FDA-2023-N-0517,** "Blood Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments."

Dear Dockets Manager:

On behalf of America's Blood Centers (ABC) and our member blood centers, we appreciate the Food and Drug Administration (FDA) holding the forthcoming public advisory committee meeting of the Blood Products Advisory Committee, and FDA's continued efforts to maintain a safe and robust blood supply.

This committee is charged with reviewing changes that can impact the "safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology" and has worked to ensure that safe blood products are available to meet patient needs. Right now, there is an immediate need to modernize the licensure process for blood centers. Modernizing the licensure process for blood centers will ensure blood and blood components are available when patients need them. The pandemic highlighted and accelerated the need to modernize the licensure process. During the pandemic, blood drive cancellations threatened the stability of the blood supply. To meet the needs of donors and hospital inventories, blood centers began to open new fixed-site locations and add automated collections to existing locations to adapt to these enduring changes. While accelerated by the pandemic, this move to more collections at fixed blood center collection facilities was a change that began before the pandemic and is likely to continue even as the pandemic wanes.

FDA regulations require licensed establishments to report changes to their approved biologics license applications (BLA) in accordance with 21 CFR 601.12. FDA's *Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods* provides guidelines specific to platelets collected by automated methods and resuspended in plasma, referred to as "Platelets, Pheresis," and includes requirements for reporting changes to an approved BLA specific to the manufacture of Platelets, Pheresis (also known as Apheresis Platelets). Of note, according to FDA's 2023 Guidance Agenda, FDA is planning to update this guidance in 2023. FDA's *Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods* provides guidelines specific to collecting single and double units of Red Blood Cells (RBC) as well as collection of co-components.

The safety history of the use of apheresis devices demonstrates that facilities can collect apheresis products at new fixed site locations without adversely impacting safety. Even though the apheresis device processes the blood and blood components collected, the substantial manufacturing steps required after collection, including infectious disease and bacterial detection testing, product modification, final labeling and storage, all occur at the manufacturing site. The manufacturing site is typically the site holding the

BLA for the manufacturing of all products collected by a blood center.

Due to this safety history, the need to ensure the availability of blood and blood components for patients, and the need for blood centers to be able to quickly fully utilize these additional collections, ABC recommends that the FDA:

1. Reclassify the reporting categories for the implementation of all types of apheresis product collections (RBC, platelets, and/or infrequent plasma) at new fixed site locations, provided that the primary facility is already approved for apheresis product they seek licensure for, from a major change to a minor change, requiring only a description in an annual report (21 CFR 601(12(d)). An inspection by FDA should not be required as part of the submission. In the alternative,
2. Reclassify the reporting categories for the implementation of all types of apheresis product collections (RBC, platelets, and/or infrequent plasma) from a major change to a moderate change, at new fixed site locations, provided that the primary facility is already approved for apheresis product they seek licensure for, without a requirement for an approved Comparability Protocol (CP), but instead requiring supplement submission at least 30 days prior to distribution of the product made using the change (CBE30) (21 CFT 601.12(c)). An inspection by FDA should not be required as part of the submission.

Thank you again for your collaborative work to ensure a safe, adequate, and available blood supply. If you have any questions or would like additional information, please contact Justine Coffey, Director, Regulatory Affairs and Public Policy, jcoffey@americasblood.org.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer