March 1, 2023

Dear Dr. Marks:

Our collective organizations would first like to thank you for the ongoing collaboration between the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) and the blood industry throughout the pandemic. We request continued open discussions and sharing of information regarding the ongoing challenges confronting the nation's blood collectors.

Over the past few years, many blood collectors have been met with significant supply chain challenges, particularly related to the availability of blood collection kits. This is largely a result of the limited number of manufacturers of whole blood and apheresis platelet collection sets licensed in the United States. Most the industry's whole blood bags were previously produced from a single manufacturing location. With so few suppliers, blood centers are unable to diversify their operation and lack sufficient contingency options. Over half of the industry has been on allocation for the past 13+ months with two of the industry's primary suppliers of whole blood bags and platelet kits. Ongoing delays in planned releases of these critical supplies require near constant management and adjustment to collections and manufacturing operations by our country's blood centers. Without active mitigation measures, these delays can have a devastating impact on the nation's blood supply.

Blood collectors have taken numerous steps to ensure that the current shortage does not impact patient care. These steps include:

- Validating additional bags, including the Fresenius Kabi CompoSelect bag manufactured in Hořátev, Czech Republic and currently approved under an Emergency Use Authorization (EUA). To date, we have moved more than two million collections to this bag, with additional transitions planned,
- Adjusting manufacturing operations to accommodate collection set changes,
- Modifying recruitment and collections activities based on the available supplies,
- Increased recruitment efforts to grow whole blood donations to supplement the lack of double red cell procedures (due to limited kit availability) or depending upon the blood center the reverse.

These changes require extensive staff time in an already challenging workforce environment and cause blood centers to incur incremental expenses. It also places pressure on donor recruitment as some centers must recruit additional donors to offset the loss of automated collections due to supply issues. Further, these changes require busy hospitals to prepare their staff and systems to accept new bags.

Given the fragility of today's supply chain, it is imperative industry join to mitigate ongoing shortages. We welcome the opportunity to collaborate with FDA and other government partners to identify solutions to prevent supply challenges in the future.

Important solutions to support the long-term stability of the blood supply chain include:

- Expedited FDA Licensure of the Fresenuis Kabi Hořátev site: The EUA is currently set to expire In December 2023. To avoid blood centers having to validate another bag option and hospitals having to ready for yet another new bag, we request licensure occur as soon as possible,

- Expedite FDA evaluation and licensure of apheresis kits and solutions to meet critical supply shortfalls to ensure clinical needs for platelets can be met,
- Allowing solutions already in use in Europe a faster path for FDA approval in the U.S. (e.g., buffy coats),
- Ensured capacity and business continuity for key suppliers in the blood industry,
- Strategic reserves of key supplies supported by the federal government.

On behalf of the industry's blood centers, we are eager to work with FDA to ensure an available blood supply to meet patient need.

Best regards,

Debra BenAvram
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