America's Blood Centers®
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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Rm 1061
Rockville, MD 20852

Submitted via https://www.regulations.gov

Re: Docket No. FDA-2022-D-0053, "Select Updates for the 506J Guidance: 506J Device List and Additional Notifications"

Dear Dr. Califf:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian, blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

FDA has developed a list of devices (506J Device List) for which a manufacturer of the listed device is required to notify the agency "at least six months in advance of a permanent discontinuance in manufacturing of a device or an interruption in manufacturing of a device that is likely to lead to a meaningful disruption in supply of the device in the United States. If that timeframe is not possible…that notification [should] be done 'as soon as practicable'."[1] These requirements are intended to help prevent or mitigate device shortages during, or in advance of, a public health emergency (PHE).

ABC appreciates FDA's publication of and solicitation of input on the 506J Device List. Notification by manufacturers of an interruption or permanent discontinuance in the manufacture of a device is essential to mitigate or avoid product shortages such as those that occurred during the COVID-19 PHE.

Devices that allow for the collection and availability of blood products are critical to public health.

Under section 506J of the Federal Food, Drug, and Cosmetic Act, "devices that are critical to public health during a PHE, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery," are subject to the permanent discontinuance or interruption in manufacturing notice requirements.[2] Devices that allow for the collection and availability of blood products are critical to public health. They ensure life-supporting, life-sustaining, and emergency blood products are available when needed.

[1] Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C act Guidance for Industry, page 4.
[2] Id.

The availability of blood components for transfusion is essential to the nation's health care system. Every two seconds in the U.S., someone needs blood. A wide range of patients depend on blood transfusions, including mothers experiencing complications during delivery, patients with cancer who require blood as part of their regular treatment regimen, individuals with chronic blood disorders who require ongoing blood transfusions to remain healthy, trauma victims who experience significant blood loss, patients who require surgery and need blood to ensure a healthy recovery, and many others.

"Blood transfusion has its greatest benefit in acute blood loss. Whether from trauma, surgery, or childbirth, bleeding patients are saved every day by transfusions. This has led to the very early use of transfusions—with the knowledge that literally minutes of delay can be fatal. This approach uses balanced ratios of RBCs for oxygen, and plasma and platelets to support blood coagulation, and…[has] led to substantial improvements in patient survival rates in acute bleeding."[3]

Over the past few years, significant supply chain challenges have at times threatened the availability of a robust blood supply. The limited number of manufacturers of whole blood and apheresis collection sets licensed in the United States, the limited number of manufacturing sites for blood bags and collection kits they operate, and the location of these sites in geographically vulnerable areas combine to pose significant concerns to the entire blood community. In addition, throughout the pandemic, blood centers experienced supply chain shortages of blood tubes, pipette tips, and personal protective equipment necessary for collecting and manufacturing blood components. Blood collectors took numerous steps to mitigate the impact of these shortages on patient care, including validating additional types of bags, adjusting manufacturing operations to accommodate collection set changes, modifying recruitment and collections activities based on available supplies, and increasing recruitment efforts to increase whole blood donations to supplement the lack of double red cell procedures (due to limited kit availability). These changes ensured continued availability of blood components to serve patients, however, they also resulted in increased costs, staff time, and increased complexity within blood center operations. While the tactics differed, ensuring a safe and adequate blood supply was always paramount.

ABC strongly recommends that FDA include devices used for the collection of blood products on the 506J Device List.

To ensure the availability of blood products during a PHE, ABC strongly recommends that FDA include the following devices used for the collection of blood products on the 506J Device List:

Part 864 Hematology and Pathology Devices

Subpart F – Automated and Semi-Automated Hematology Devices:
864.5200 Automated Cell Counter {GKL}
864.5600 Automated Hematocrit Instrument {GKF}
864.5620 Automated Hemoglobin System {GKR}

Subpart H – Hematology Kits and Packages
864.7825 Sickle cell test {JBB}

Subpart J - Products Used in Establishments That Manufacture Blood/Blood Products
864.9050 Blood Bank Supplies (pipettes, blood grouping slides, blood typing tubes and racks, cold packs for antisera reagents). {KSS}
864.9100 Empty container for the collection and processing of blood and blood components {KSR}

[3] "Value of Blood to the U.S. Healthcare System," America's Blood Centers, 2019, page 7.

864.9125 Vacuum-assisted blood collection system. {KST}
864.9145 Processing system for frozen blood (for both freezing and thawing red blood cells) {KSW}
864.9175 Manual blood grouping and antibody test systems. {PBC}
864.9195 Blood mixing devices and blood weighing devices. {KSQ}
864.9245 Automated blood cell separator (apheresis devices). {GKT}
864.9275 Blood bank centrifuge for in vitro diagnostic use. {KSO}
864.9575 Environmental chamber for storage of platelet concentrate. {KSH}
864.9700 Blood storage refrigerator and blood storage freezer. {KSE}
864.9750 Heat-sealing device (also sterile docking devices). {KSD}
864.9875 Transfer set. {KSB}

ABC appreciates the opportunity to comment on the Draft Guidance. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

Thank you for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer