U.S. Food and Drug Administration

Current Good Manufacturing Practices and Related Regulations
for Blood and Blood Components;
and Requirements for Donor Testing, Donor Notification,
and "Lookback"

OMB Control No. 0910-0116

Non-substantive Change Request:

FDA is requesting a non-substantive change to OMB Control No. 0910-0116, which supports the above-captioned FDA regulations for blood and blood components. The discussion below regarding notification to consignees was inadvertently omitted in our change request of December 11, 2018, along with the notification item we did discuss. In addition to the current good manufacturing practice regulations for blood and blood components in 21 CFR part 606, there are regulations in 21 CFR part 630 that include requirements for blood and blood components intended for transfusion or further manufacturing use, and in 21 CFR part 640 that require additional standards for certain blood and blood products. These regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components.

In the Federal Register of December 6, 2018 (83 FR 62873), we published a notice announcing the availability of a draft document entitled "*Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry*" ("Bacterial draft guidance"). The Bacterial draft guidance provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion.

As stated in the Bacterial draft guidance, platelets may only be stored beyond day 5 and up to day 7 if certain conditions are met. To store platelets up to 7 days, each platelet product must be tested using a bacterial detection device cleared by FDA and labeled for use as a "safety measure" according to its instructions for use. Furthermore, the platelet storage container being used to store such platelets must be FDA cleared or approved for 7-day storage. We recommend blood establishments communicate to their consignees the type of storage container the platelets are stored in, for example, a storage container approved for 5-day storage or storage container approved for 7-day storage. This recommendation will help to ensure that only platelets stored in appropriately labeled containers are labeled with a 7-day expiration date.

FDA is in the process of finalizing the Bacterial draft guidance, which must be published by September 30, 2019 in order to comply with an appropriations rider in FDA's Fiscal Year 2019 Appropriations Act. Therefore, we are requesting that the recommendation in the guidance for blood establishments to communicate to consignees the type of storage container

the platelets are stored in (for example, a storage container approved for 5-day storage or storage container approved for 7-day storage), as discussed above, be included in this approved collection of information since this notification is considered usual and customary business practice. We attribute burden in the amount of one hour and one response annually for the information collection recommendation included in the draft Bacterial guidance.

Dated: August 2019