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. 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Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry*" ("Bacterial draft guidance"). The Bacterial draft guidance provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature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As stated in the Bacterial draft guidance, blood collection establishments and transfusion services should have in place measures to promptly alert the collection establishment or transfusion service if a distributed platelet product is subsequently identified as positive for bacterial contamination. Under 21 CFR 606.145(c), a transfusion service must notify the blood collection establishment that provided the platelets in the event the transfusion service identifies platelets as bacterially contaminated. FDA, in the Bacterial draft guidance, recommends blood collection establishments notify transfusion services to provide this same information. Although such notifications occur infrequently, we believe that these notification practices are currently part of the usual and customary business practice for blood collection establishments because blood collection establishments are required under 21 CFR 606.100(b)(22) to establish procedures to control the risk of bacterial contamination, including all steps required under 21 CFR 606.145. The collection of information under 21 CFR 606.100(b) is covered in this OMB package.

After we consider any public comments received, we intend to finalize the Bacterial draft guidance. Therefore, we are requesting that the recommendation in the guidance for blood establishments to notify transfusion services, as discussed above, be included in this approved collection of information since the usual and customary information collection activity contained in the draft bacterial guidance is similar to that contained under 21 CFR 606.145(c). 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: December 2018