AABB NewsFlash

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FDA Announces Revised Timeline for Guidance on Bacterial Risk Control Strategies for Platelets

FDA released today a revised version of its "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Guidance for Industry." The revised guidance is updated to address the challenges blood centers face with implementation during the ongoing COVID-19 pandemic. Section IV of the guidance now includes a revised recommended implementation date, stating "prior to October 1, 2021 as a reasonable timeframe for implementation."

In the revised guidance, the agency acknowledged the ongoing COVID-19 pandemic affected blood centers' ability to comply with the initial implementation date. "We received numerous comments from blood collection establishments requesting an extension of the implementation timeframe because of various unforeseen challenges, including responding to the COVID-19 public health emergency," the revised guidance states. "Consequently, we have extended the recommended implementation timeframe in section VI. of the guidance. In addition, we clarified the recommendations for submission of information in a prior approval supplement submission in section IV.A.2.f. and g. of the guidance. We also removed a footnote regarding the lack of appropriately labeled devices for implementation of the large volume, delayed sampling no sooner than 48 hours strategy for a 7-day dating period in section III.B.1.b. of the guidance because of a recent device clearance."

AABB applauds the agency's decision and support of the blood community amidst the unprecedented challenges facing hospital transfusion services and blood donor centers. Claudia Cohn, MD, PhD, AABB's chief medical officer, said the revised timeline was important, given the ongoing challenges the blood community faces as it responds to the COVID-19 pandemic. "The FDA guidance for bacterial risk control strategies for platelets was finalized in September 2019," Cohn said. "At that time, it was the biggest news for most blood centers, and they immediately began to lay plans to develop and implement necessary changes to their workflows. No one in September 2019 could have known that our world would be turned upside down by a novel coronavirus. Since early 2020, the blood community has worked tirelessly to deal with the ongoing COVID-19 pandemic, with blood centers diverting their time and energy toward COVID-19 convalescent plasma collection while hospitals raced to find new ways to treat the high number of patients filling their ICUs. I think we are all grateful to the FDA for allowing this delay, which will give blood centers and hospitals time to recover and be better prepared for the changes to come."

Read more about this topic on the AABB Newsfeed.

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