DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1814]

Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''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 guidance document provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion. The recommendations in the guidance apply to all platelet products stored at room temperature in plasma or additive solutions, including platelets manufactured by automated methods (apheresis platelets), and Whole Blood derived (WBD) single and pooled (pre-storage and post-storage) platelets. Additionally, the guidance provides licensed blood establishments with recommendations on how to report implementation of manufacturing and labeling changes. The guidance announced in this notice finalizes the draft guidance of the same title dated December 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 2, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1814 for ''bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''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 guidance document provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion. The recommendations in the guidance apply to all platelet

products stored at room temperature in plasma or additive solutions, including platelets manufactured by automated methods (apheresis platelets), and WBD single and pooled (pre-storage and post-storage) platelets. Additionally, the guidance provides licensed blood establishments with recommendations on how to report implementation of manufacturing and labeling changes.

Room temperature stored platelets are associated with a higher risk of sepsis and related fatality than any other transfusable blood component. The risk of bacterial contamination of platelets is a leading risk of infection from blood transfusion, and this risk has persisted despite the implementation of numerous interventions, including a commonly used method of a single culture test after collection of the platelets.

FDA has established regulations to address the control of bacterial contamination of platelets. Under 21 CFR 606.145(a), blood establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices, or other adequate and appropriate methods found acceptable for this purpose by FDA. The guidance provides recommendations to control the risk of bacterial contamination of platelets with 5-day and 7-day dating, including bacterial testing strategies (using culture-based and rapid bacterial detection devices) and the implementation of pathogen reduction devices. In the **Federal Register** of December 6, 2018 (83 FR 62872), FDA announced the availability of the revised draft guidance of the same title dated December 2018. FDA received numerous comments on the draft guidance, including comments on the potential impact of the recommendations on platelet availability, and those comments were considered as the guidance was finalized. In response to comments, the final guidance provides recommendations for additional culture-based testing strategies for apheresis platelets and pre-storage pools of WBD platelets and revised recommendations for testing single unit and post-storage pools of WBD platelets. In addition, revisions were made to clarify recommendations related to labeling, dating periods, inventory management, and culture incubation periods. The guidance announced in this notice finalizes the draft guidance dated December 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 601 and 610 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR part 607 have been approved under OMB control number 0910–0052.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov*.

Dated: September 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21228 Filed 10–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0573]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (BPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues related to blood and products derived from blood. The committee will discuss scientific considerations for cold stored platelet products intended for transfusion. The meeting will be open to the public.

DATES: The meeting will be held on November 22, 2019, from 8:30 a.m. to 4:45 p.m.

ADDRESSES: Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20993. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*. Information about the Tommy Douglas Conference Center may be accessed at: *https://www.tommydouglascenter.com/*.

For those unable to attend in person, the meeting will also be webcast; please see the following link for webcast and other meeting information: *https://www.fda.gov/advisory-committees/blood-products-advisory-committee/2019-meeting-materials-blood-products-advisory-committee*.

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, *christina.vert@fda.hhs.gov,* or 240–402–8106, *joanne.lipkind@fda.hhs.gov,* respectively, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 22, 2019, the BPAC will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and