



4164-01-P

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Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry; Availability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 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Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry.” The draft guidance document provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room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 through the implementation of pathogen reduction technology (PRT) or bacterial testing. The draft guidance also provides recommendations for the use of secondary testing of platelets as the basis to extend the dating period of platelets, when appropriately labeled bacterial detection devices and storage containers are used. The draft guidance replaces the draft guidance entitled “Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,” dated December 2014. The draft guidance, when finalized, is intended to supersede the recommendation in section VII.A.2, in regard to bacterial

contamination testing in the document entitled “Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods” dated December 2007.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft 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 draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Information Collection Requirements: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

Guidance Document: Jonathan McKnight, 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 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.” Platelets are associated with a higher risk of sepsis and are related to more fatalities than any other transfusable blood component. The risk of bacterial contamination of platelets is a leading risk of infection from blood transfusion. This risk has persisted despite numerous interventions including the introduction, in the last decade, of analytically sensitive culture-based bacterial detection methods, which are widely used to test platelets prior to their release from blood collection establishments to transfusion services.

The 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 through the implementation of PRT or bacterial testing. PRT is performed shortly after platelet collection by blood collection establishments. Bacterial testing encompasses primary testing of platelets by blood collection establishments and subsequent secondary testing prior to transfusion primarily by transfusion services. The draft guidance also

provides recommendations for the use of secondary testing of platelets as the basis to extend the dating period of platelets, when appropriately labeled bacterial detection devices and storage containers are used. Additionally, the draft guidance provides recommendations to licensed blood establishments for submitting biologics license application supplements to include bacterial testing of platelet components. The guidance informs transfusion services that are currently exempt from registration and blood product listing that if they choose to perform secondary testing of platelets to extend the dating period, they must register with FDA and list the blood products they manufacture.

The draft guidance applies to all platelet products, including platelets manufactured from Whole Blood (Whole Blood Derived (WBD) platelets), platelets collected by automated methods from a single donor (apheresis platelets), pooled platelets, and platelets stored in additive solutions.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep

records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion

Description: We have identified the following recommendations in the draft guidance document as collections of information. In section VI, the draft guidance recommends that blood collection establishments have in place measures to promptly alert the transfusion services in the event that a distributed platelet product is subsequently identified as positive for bacterial contamination. In section X.A.2, the draft guidance recommends that following secondary testing, labeling on the container label or a tie-tag, should relay the following information: (1) Type of bacterial detection test performed (rapid or culture) and (2) the date and time the bacterial detection test was performed.

Description of Respondents: The third-party disclosure recommendations described in the draft guidance affect blood collection establishments and transfusion services that collect and manufacture platelet products for transfusion, including WBD platelets, apheresis platelets, pooled platelets, and platelets stored in additive solutions.

Burden Estimate: The Agency believes the information collection provision for blood collection establishments in section VI does not create a new burden for respondents and is part of usual and customary business practice. Blood collection establishments currently have in place standard operating procedures for notifying consignees (transfusion services) if a distributed platelet product has subsequently tested positive for bacterial contamination.

In section X.A.2, the draft guidance recommends that following secondary testing, establishments should maintain a labeling process that relays certain information and is integral to the container (e.g., on the container label or an attached tie-tag) and label accordingly. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Section X.A.2: Following secondary testing, maintain a labeling process that relays certain information and is integral to the container (e.g., on the container label or an attached tie-tag) and label accordingly.	2480	403	1,000,000	.05 (3 minutes)	50,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 provides an estimate of the annual third-party disclosure burden for the information to be submitted in accordance with the draft guidance. Based on FDA data and information submitted by industry, FDA believes that there are approximately 2 million platelet transfusions per year. The recommendation for labeling following secondary testing applies to approximately 4,960 transfusion services in the United States. We estimate that about 50

percent of all platelets will be pathogen-reduced and 50 percent will be cultured. Therefore, to estimate the annual third-party disclosure burden in table 1, we assume that approximately one-half of the transfusion services will label one-half of the total platelets intended for transfusion in the United States following secondary testing. The average burden disclosure for transfusion services to implement the recommendation in table 1 is based on FDA's experience and industry information.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.65, 606.100, 606.120, 606.121, 606.122, and 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.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the PRA (44 U.S.C.) 3407(d)), the Agency has submitted the information collection provisions of this document to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-05718 Filed: 3/14/2016 8:45 am; Publication Date: 3/15/2016]