Dated: December 2, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28713 Filed 12–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1814]

Bacterial Detection Testing by 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Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry; Availability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.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document 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 The draft guidance document provides blood collection establishments and transfusion services with recommendations for initial testing (primary testing) for bacterial contamination of platelets intended for transfusion, and provides additional considerations for blood collection establishments and transfusion services for subsequent retesting (secondary testing) of platelets prior to transfusion. The recommendations for primary testing of platelets and the additional considerations for secondary testing of platelets described in this guidance are expected to enhance the detection of bacteria in platelet products and thus enhance transfusion safety. The draft guidance, when finalized, is intended to supersede the recommendation in section VII.A.2, in regard to bacterial contamination testing in the document entitled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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 9, 2015. Submit either electronic or written comments on the collection of information by February 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New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 240–402–7800. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance and information collection to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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 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 document provides blood collection establishments and transfusion services with recommendations for primary testing for bacterial contamination of platelets intended for transfusion and additional considerations for blood collection establishments and transfusion services for secondary testing of platelets prior to transfusion. FDA also provides recommendations to licensed blood establishments for submitting Biologics License Application supplements to include bacterial testing of platelet components. Furthermore, 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, should this option become available, they must register with FDA and list the blood products they manufacture.

The draft guidance addresses 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 recommendations for primary testing of platelets and the additional considerations for secondary testing of platelets described in this guidance are expected to enhance the detection of bacteria in platelet products and thus enhance transfusion safety. 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.

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 stands out as 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 is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 collections of information set forth in this document.

With respect to the following collections 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.

Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion

We have identified the following recommendations in the draft guidance document as collections of information. In section V, 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 IX.A.2, the draft guidance recommends that following secondary testing, a tie-tag should be attached to the platelet products to relay the following information: Type of bacterial detection test performed (rapid or culture); date and time the bacterial detection test was performed; and, the results of the bacterial detection testing. The draft guidance also recommends that a single tie-tag may be attached to a pooled platelet product.

Description of Respondents: The third-party disclosure and one-time recordkeeping recommendations described in the draft guidance affect blood collection establishments and transfusion services that collect and manufacture platelet products for transfusion, including WBD platelets, platelets collected by automated methods from a single donor (apheresis platelets), pooled platelets, and platelets stored in additive solutions.

Burden Estimate: The Agency believes the information collection provision for licensed blood collection establishments in section V 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 IX.A.2, the draft guidance recommends that following secondary testing, a tie-tag should be attached to the platelet products to relay certain information related to the bacterial detection test. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Under section IX.A.2, a tie-tag to the platelet product relaying specific information following secondary testing should be attached	150	1,250	187,500	.05	9,375

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

Table 1 of this document 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 and that 75 percent or 1.5 million transfusions occur at large volume transfusion services. FDA also believes that on average, the large volume transfusion services perform about 5,000 platelet transfusions annually. Furthermore, FDA approximates that 150 transfusion services, most of which will be large volume transfusion services, may elect to perform secondary testing. We expect that secondary testing will be used primarily for the extension of dating up to 7 days at large volume transfusion services. However, while each of the 150 transfusion services may issue, on average, 5,000 platelets a year, secondary testing will be performed on only a portion of these platelets. Based on FDA experience, we estimate that secondary testing will be performed on approximately 25 percent or 1,250 platelets to permit transfusion beyond day 5. Thus, the total estimated annual burden of 9,375 hours for transfusion services to implement the recommendation in Table 1 is based on FDA's experience and industry information.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Creation of SOPs	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Under section IX.A.2, a tie-tag to the platelet product relaying specific information following secondary testing should be attached.	150	1	150	16	2,400

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

Table 2 of this document provides a one-time recordkeeping burden estimate for the information to be submitted in accordance with the draft guidance. As described in the proceeding paragraphs, based on FDA's experience and industry information, FDA anticipates that 150 respondents, mainly from large volume transfusion services, will implement the recommendations set forth in section IX.A.2. Thus, based on FDA data and industry recordkeeping information, FDA estimates that the total estimated one-time recordkeeping burden is 2,400 hours.

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 606.140 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 607.3, 607.7 and 607.65 have been approved under OMB control number 0910–0052.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. 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: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28809 Filed 12–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2083]

Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.'' This draft guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). The draft guidance describes FDA's expectations for prescription drug wholesale distributors (wholesale distributors) and third-party logistics providers (3PLs) about reporting to FDA under the DSCSA.

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 February 9, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 4147, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *wdd3plrequirements@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers.'' This guidance is being issued to facilitate implementation of new reporting provisions under the DSCSA. On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines new requirements for the licensing of prescription drug wholesale distributors and 3PLs.

Section 204 of the DSCSA amends section 503(e) of the FD&C Act (21 U.S.C. 353(e)) and outlines requirements for reporting by wholesale distributors. Section 503(e)(2)(A) of the FD&C Act (as amended) requires wholesale distributors to report annually, beginning on January 1, 2015. Information to be reported includes State licensure information and contact information for each facility. Wholesale distributors are also to report to FDA any significant disciplinary actions taken by the State or Federal Government, such as revocation or suspension of a license. Section 204 of the DSCSA also amends section 503(e)(2)(B) of the FD&C Act and requires FDA to make information about wholesale distributors' licensure available to the public on FDA's Web site. Updates to the public information are to be made on a schedule to be determined by FDA.

Section 205 of the DSCSA adds section 584 to the FD&C Act. Section 584 sets forth requirements for licensure and reporting by 3PLs. Under section 584 of the FD&C Act (as amended) (21 U.S.C. 360eee–3), 3PLs are required to report annually to FDA, beginning on November 27, 2014 (1 year after the date of enactment of the DSCSA). Third-party logistic providers are required to report State licensure information, name and address for each facility, and all trade names under which each facility conducts business.