Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/ Route	Applicant
NDA 011602	KENALOG	Triamcinolone Acetonide.	0.025%; 0.1%	Lotion; Topical	Delcor Asset Corp.
NDA 016059	INDOCIN	Indomethacin	25 milligrams (mg); 50 mg	Capsule; Oral	Iroko Pharmaceuticals, LLC.
NDA 017560	BACTRIM and BACTRIM PEDIATRIC.	Sulfamethoxazole; Trimethoprim.	200 mg/5 milliliters (mL); 40 mg/5 mL	Suspension; Oral	Mutual Pharmaceutical Company, Inc.
NDA 017598	SEPTRA and SEPTRA GRAPE.	Sulfamethoxazole; Trimethoprim.	200 mg/5 mL; 40 mg/5 mL	Suspension; Oral	Monarch Pharmaceuticals, Inc.
NDA 018185	INDOCIN SR	Indomethacin	75 mg	Extended-Release Capsule; Oral.	Iroko Pharmaceuticals, LLC.
NDA 018450	NITROPRESS	Sodium Nitroprusside.	50 mg/vial	Injectable; Injection.	AbbVie Inc.
NDA 019834	PLENDIL	Felodipine	2.5 mg; 5 mg; 10 mg	Extended-Release Tablet; Oral.	AstraZeneca.
NDA 021475	METHYLIN	Methylphenidate Hydrochloride.	2.5 mg; 5 mg; 10 mg	Chewable Tablet; Oral.	Mallinckrodt Pharmaceuticals.
NDA 050320	UNIPEN	Nafcillin Sodium	Equal to (EQ) 500 mg base/vial; EQ 1 g (gram) base/vial; EQ 2 g base/vial; EQ 4 g base/vial; EQ 10 g base/vial; EQ 20 g base/vial.	Injectable; Injection.	Wyeth Ayerst Pharmaceuticals.
NDA 050406	KEFLEX	Cephalexin	EQ 125 mg base/5 mL; EQ 250 mg base/5 mL; EQ 100 mg base/mL.	For Suspension; Oral.	Shionogi Inc.
ANDA 060576	MYCOLOG–II	Nystatin; Triamcinolone Acetonide.	100,000 units/g; 0.1%	Cream; Topical	Delcor Asset Corp.
ANDA 062117	CEPHALEXIN	Cephalexin	EQ 125 mg base/5 mL; EQ 250 mg base/5 mL; EQ 100 mg base/mL.	For suspension; Oral.	Facta Farmaceutici S.p.A.
ANDA 062606	MYCOLOG–II	Nystatin; Triamcinolone Acetonide.	100,000 units/g; 0.1%	Cream; Topical	Delcor Asset Corp.
ANDA 062717	UNIPEN	Nafcillin Sodium	EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Injectable; Injection.	Wyeth Ayerst Pharmaceuticals.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05717 Filed 3–14–16; 8:45 am]

BILLING CODE 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 June 13, 2016. Submit either electronic or written comments on the collection of information by May 16, 2016.

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, *PRAStaff@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 BURDEN [1]

Activity	Number of respondents	Number 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 Unites 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 3–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 14, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0625. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission of Medical Device Registration and Listing—21 CFR Part 807, Subparts A Through D; OMB Control Number 0910–0625—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) and part 807, subparts A through D (21 CFR part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) Identification of establishments producing marketed medical devices, (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, (3) facilitation of recalls for devices marketed by owners and operators of device establishments, (4) identification and cataloguing of marketed devices, (5) administering postmarketing surveillance programs for devices, (6) identification of devices marketed in violation of the law, (7) identification and control of devices imported into the country from foreign establishments, (8) and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System.

Burden estimates are based on recent experience with the existing medical device registration and listing program, electronic system operating experience, and the economic analysis for the final rule entitled ''Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007.''

In the **Federal Register** of October 27, 2015 (80 FR 65779), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.20(a)(5) [2]—Submittal of manufacturer information by initial importers.	3673	8,594	1	8,594	1.75	15,040
807.20(a)(5) [3]—Submittal of manufacturer information by initial importers.	3673	8,594	3	25,782	.1 ..... (6 minutes)	2,578