Authority: Section 1110 of the Social Security Act.

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–20068 Filed 9–14–18; 8:45 am]

BILLING CODE 4184–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2973]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA research in obtaining information from medical specialty groups and/or medical experts regarding compounded drug products that contain certain bulk drug substances to support establishment of a list of bulk drug substances under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by November 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2018–N–2973 for ''Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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.

Clinical Use of Bulk Drug Substances Nominated for Use in Compounding by Outsourcing Facilities

OMB Control Number 0910—NEW

This information collection supports Agency-sponsored research. Section 503B of the FD&C Act requires FDA to develop a list of bulk drug substances that may be used in compounding under that section (503B bulks list). Compounding includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug. If certain conditions are met, drug products compounded by entities known as outsourcing facilities are exempt from the following requirements of the FD&C Act: Requirements for FDA approval of drugs, labeling with adequate directions for use, and drug supply chain security requirements. Outsourcing facilities can only use a bulk drug substance to compound drugs if: (1) The substance appears on a list developed by FDA of bulk drug substances for which there is a clinical need (''bulks list'') or (2) the substance is used to compound a drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

Many bulk drug substances have been nominated by the public for use in compounding by outsourcing facilities with adequate supporting information for FDA to evaluate them. The substances were nominated to treat a variety of conditions, ranging in degree of severity from treatment of warts to treatment of cancer. To inform our evaluation of bulk drug substances for inclusion on the 503B bulks list, we have proposed a research study with the University of Maryland (UMD) Center of Excellence in Regulatory Science and Innovation (CERSI) and the Johns Hopkins University (JHU) CERSI. We intend to seek input from the CERSI–UMD on the use of these bulk drug substances in clinical practice by examining their current and historical use in compounding. Information regarding the historical and current use of the substances in compounding obtained by this research will help inform our assessments as to the clinical need for outsourcing facilities to use the substance in compounding.

FDA's analysis concerning clinical need of nominated bulk drug substances consists of two parts. The collaboration with CERSI–UMD and CERSI–JHU pertains to part 2 of the analysis, which applies to bulk drug substances that are not components of FDA-approved drug products, as well as certain bulk drug substances that are components of FDA-approved drug products and have successfully completed part 1. One of the factors that FDA considers under part 2 is ''current and historical use of the substance in compounded drug products, including information about the medical condition(s) that the substance has been used to treat and any references in peer-reviewed medical literature.''

As needed, researchers will also engage outsourcing facilities that have compounded using the bulk drug substance. Researchers may use surveys, interviews, focus groups, and other information collect tools, as appropriate, to obtain information concerning the use of compounded product(s) from medical experts and outsourcing facilities. Within this context, the following questions may be posed:

1. What are the health conditions that the compounded drug is currently and has been historically used to treat? What is the patient population for which the compound drug has been used to treat?

2. What are the characteristics of the compounded drugs using the bulk drug substance (*e.g.,* dosage form, strength, route of administration)?

3. Is the compounded drug considered standard therapy by healthcare practitioners, and is it recommended in clinical practice guidelines? If so, under what circumstances?

4. Does an approved drug exist for the health condition that the compounded drug product is used to treat? If so, what are the circumstances under which a compounded drug product using the bulk drug substance would be used in lieu of the approved drug product?

5. What is the historical use of the compounded drug to treat the health conditions identified, including the number of years during which the compounded drug has been prescribed for each use, and any change regarding its use over time?

6. To what extent do practitioners prescribe the compounded drug to treat each health condition identified? How many such prescriptions and/or orders have been written in the past 5 years? Have there been any notable changes in the number of prescriptions and/or orders written over this time?

7. How widespread is the use of the compounded drug product, including use in other countries?

8. Do practitioners order the compounded drug to maintain on hand before a patient presents with a need for the drug (''office stock''), or do practitioners typically write prescriptions for a patient after the patient presents with a need for the compounded drug? If the former, why (*e.g.,* emergency situations, convenience)?

9. What, if any, information exists regarding the effectiveness of the compounded drug product in treating the specified health condition?

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups and interviews	150	10	1,500	2	3,000

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

We base our estimate of the average burden per response on review activities familiar to the Agency. Noting that 2 hours per response is a significant amount of time, we are particularly interested in feedback regarding this estimate, including comments regarding how an alternative estimate might be derived.

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20092 Filed 9–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3431]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of September 11, 2018. The document announced a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and establishment of a public docket for comments. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, September 11, 2018 (83 FR 45941), in FR Doc. 2018–19667, on page 45941, the following correction is made:

On page 45941, in the first column, in the header of the document, and also in the third column under *Instructions,* ''Docket No. FDA–2018–N–3276'' is corrected to read ''Docket No. FDA–2018–N–3431''.

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20091 Filed 9–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3236]

Advisory Committee; Oncologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until September 1, 2020.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *ODAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Oncologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Oncologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner.

The committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm107395.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20108 Filed 9–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Pathogen Reduction Technologies for Blood Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Pathogen Reduction Technologies for