ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Project Outcome Assessment Survey	85	1	6	510

Estimated Total Annual Burden Hours: 510.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09413 Filed 5–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2973]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 June 7, 2019.

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–NEW and title ''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.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

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 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) requires FDA to develop a list of bulk drug substances that may be used in compounding under that section (503B bulks list). Section 503B defines compounding to include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug. Compounded drugs are not FDA-approved. If the conditions under section 503B 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 in section 505 of the FD&C Act (21 U.S.C. 355), labeling with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and drug supply chain security requirements under section 582 (21 U.S.C. 360eee-1). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility may not compound a drug using a bulk drug substance unless (1) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need (''bulks list''); or (2) the substance appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) 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. To inform our evaluation of bulk drug substances for inclusion on the 503B bulks list, we have entered into 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.

FDA intends to use a two-part analysis in evaluating substances nominated for placement on the 503B bulks list to determine whether there is a clinical need. 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 that have gone through part 1 and warrant further evaluation under part 2 of the analysis. 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.''

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, outsourcing facilities, and other stakeholders. Within this context, the following questions may be posed:

1. What are the health condition(s) 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 drug(s) using the bulk drug substance (*e.g.,* dosage form, strength, route of administration)?

3. Is the compounded drug considered standard therapy by healthcare practitioners, or 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)?

In the **Federal Register** of September 17, 2018 (83 FR 46957), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, and FDA determined that this comment was applicable to a different docket published in the **Federal Register**, and not relevant to this proposed collection of mation.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
UMD–CERSI Expert Focus Groups and Interviews	150	10	1,500	2	3,000
UMD–CERSI Expert Questionnaire	750	10	7,500	*0.5	3,750
JHU–CERSI Parent Questionnaire	1,000	1	1,000	*0.5	500
Total	7,250				

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

We base our estimate of the average burden per response on review activities familiar to the Agency. Since issuing the 60-day notice, FDA determined an additional burden estimate related to completion of questionnaires. We welcome additional comments regarding this estimate.

Dated: May 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09414 Filed 5–7–19; 8:45 am]

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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 June 7, 2019.

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 (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