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]

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 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

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 previous data estimates.

In the **Federal Register** of December 4, 2018 (83 FR 62583), 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	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.20(a)(5) [2]—Submittal of Manufacturer Information by Initial Importers	3673	5,736	1	5,736	1.75	10,038
807.20(a)(5) [3]—Submittal of Manufacturer Information by Initial Importers	3673	5,736	1	5,736	0.1	574
807.21(a) [2]—Creation of Electronic System Account	3673	2,937	1	2,937	0.5	1,469
807.21(b) [3]—Annual Request for Waiver from Electronic Registration and Listing	.....	1	1	1	1	1
807.21(b) [2]—Initial Request for Waiver from Electronic Registration and Listing for	.....	1	1	1	1	1
807.22(a) [2]—Initial Registration and Listing	3673	3,467	1	3,467	1	3,467
807.22(b)(1) [3]—Annual Registration	3673	23,403	1	23,403	0.5	11,702
807.22(b)(2) [3]—Other Updates of Registration	3673	2,687	1	2,687	0.5	1,344
807.22(b)(3) [3]—Annual Update of Listing Information	3673	22,607	1	22,607	0.5	11,304
807.26(e) [3]—Labeling and Advertisement Submitted at FDA Request	.....	71	1	71	1	71
807.34(a) [2]—Initial Registration and Listing when Electronic Filing Waiver Granted	.....	1	1	1	1	1
807.34(a) [3]—Annual Registration and Listing when Electronic Filing Waiver Granted	.....	1	1	1	1	1
807.40(b)(2) [3]—Annual Update of US Agent Information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) [3]—US Agent Responses to FDA Requests for Information	3673	1,535	1	1,535	0.25	384
807.41(a) [3]—Identification of Initial Importers by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
807.41(b) [3]—Identification of Other Parties that Facilitate Import by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
Total One Time Burden	.....	.....	.....	.....	.....	14,975
Total Recurring Burden	.....	.....	.....	.....	.....	39,173

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals are rounded to the nearest whole number.
[3] One-Time Burden—Firm only provides initially.
[4] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) [2]—List of Officers, Directors, and Partners	22,338	1	22,338	0.25 (15 minutes)	5,585
807.26 [2]—Labeling and Advertisements Available for Review.	17,032	4	68,128	0.5 (30 minutes)	34,064
Total	.....	.....	.....	.....	39,649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

The following adjustments and program changes resulted in a 5,672-hour decrease to the overall total hour burden estimate for this information collection request.

- We adjusted the number of respondents based on updated registration and listing data.
- In the reporting burden table, we corrected the table footnotes to accurately indicate whether the information collection (IC) is a one-time or reoccurring burden.
- We also adjusted some of the IC descriptions in the table for increased clarity.
- We updated our estimate of Hours per Response for ''807.22(a) Initial Registration and Listing'' (+ 0.5 hours), ''807.22(b)(1) Annual Registration'' (− 0.25 hours), and ''807.22(b)(3) Annual Update of Listing Information'' (− 0.25 hours). Based on our review of the program, we believe these changes to the burden estimate will more accurately reflect the current preparation time for these ICs.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09412 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–7011]

Laser Products—Conformance With IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56); Guidance for Industry and Food and Drug Administration Staff; 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 final guidance for industry entitled ''Laser Products—Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56).'' This guidance describes the Agency's approach regarding compliance with FDA's performance standards for laser products. FDA believes that under the circumstances described in this guidance, conformance with certain International Electrotechnical Commission (IEC) standards would provide adequate protection of the public health and safety for laser products similar to performance standards in FDA's regulations. Accordingly, for laser product manufacturers that comply with the comparable clauses in IEC standards specified in the guidance, FDA does not intend to enforce the specified laser performance standards in FDA's regulations.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2017–D–7011 for ''Laser Products—Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56).'' Received comments 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