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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.21(a) [3]—Creation of electronic system account.	3673	3,559	1	3,559	.5 (30 minutes)	1,780
807.21(b) [2]—Annual request for waiver from electronic registration and listing.		14	1	14	1	14
807.21(b) [3]—Initial request for waiver from electronic registration and listing.		4	1	4	1	4
807.22(a) [3]—Initial registration and listing	3673	3,539	1	3,539	.5 (30 minutes)	1,770
807.22(b)(1) [3]—Annual registration	3673	20,355	1	20,355	.75 (45 minutes)	15,266
807.22(b)(2) [3]—Other updates of registration.	3673	4,176	1	4,176	.5 (30 minutes)	2,088
807.22(b)(3) [3]—Annual update of listing information.	3673	19,875	1	19,875	1	19,875
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.		14	1	14	1	14
807.34(a) [3]—Annual registration and listing when electronic filing waiver granted.		4	1	4	1	4
807.40(b)(2) [3]—Annual update of U.S. agent information.	3673	1,615	1	1,615	.5 (30 minutes)	808
807.40(b)(3) [3]—U.S. agent responses to FDA requests for information.	3673	1,535	1	1,535	.25 (15 minutes)	384
807.41(a) [3]—Identification of initial importers by foreign establishments.	3673	10,329	1	10,329	.5 (30 minutes)	5,165
807.41(b) [3]—Identification of other parties that facilitate import by foreign establishments.	3673	10,329	1	10,329	.5 (30 minutes)	5,165
Total one-time burden						15,068
Total recurring burden						54,958

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.
[3] Recurring burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d) [2]—List of officers, directors and partners	23,806	1	23,806	.25 (30 minutes)	5,952
807.26 [2]—Labeling and advertisements available for review.	11,746	4	46,984	.5 (30 minutes)	23,492
Total					29,444

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

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05744 Filed 3–14–16; 8:45 am]

BILLING CODE 4164–01–P