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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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.	No. 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	No. 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.

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