



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-N-1330]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submissions 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:** Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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

This information collection supports FDA statutes and regulations. 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](#), [B](#), [C](#), and 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 cataloging of marketed devices, (5) administering post marketing 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 (FURLS).

In the *Federal Register* of June 20, 2025 (90 FR 26304), 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

21 CFR Part FDA Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
807.20(a)(5) <sup>2</sup> Initial Submittal of Manufacturer Information by Initial Importers (FDA 3673)	2,219	1	2,219	1.75	3883
807.20(a)(5) <sup>3</sup> Annual Submittal of Manufacturer Information by Initial Importers (FDA 3673)	2,219	1	2,219	0.1	222
807.21(a) <sup>2</sup> Creation of electronic system account (FDA 3673)	8,876	1	8,876	0.5	4,438
807.21(b) <sup>3</sup> Annual Request for Waiver from Electronic Registration & Listing	1	1	1	1	1
807.21(b) <sup>2</sup> Initial Request for Waiver from Electronic Registration & Listing	1	1	1	1	1
807.22(a) <sup>2</sup> Initial Registration & Listing (FDA 3673)	2,106	1	2,106	1	2,106
807.22(b)(1) <sup>3</sup> Annual Registration (FDA 3673)	30,280	1	30,280	0.5	15,140
807.22(b)(2) <sup>3</sup> Other updates of Registration (FDA 3673)	3,906	1	3,906	0.5	1,953
807.22(b)(3) <sup>3</sup> Annual Update of Listing Information (FDA 3673)	28,925	1	28,925	0.5	14,463
807.22(b)(4) Changes to listing information (outside of annual listing requirement period)					
Voluntary reporting of transfer of 510(k) clearance in FURLS (outside of annual listing requirement period)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132

Table 1.--Estimated Annual Reporting Burden

21 CFR Part FDA Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
807.26(e) <sup>3</sup> Labeling & Advertisement Submitted at FDA Request	1	1	1	1	1
807.34(a) <sup>2</sup> Initial Registration & Listing when Electronic Filing Waiver Granted	1	1	1	1	1
807.34(a) <sup>3</sup> Annual Registration & Listing when Electronic Filing Waiver granted	1	1	1	1	1
807.40(b)(2) <sup>3</sup> Annual Update of US Agent Information (FDA 3673)	3,410	1	3,410	0.5	1,705
807.40(b)(3) <sup>3</sup> US Agent Responses to FDA Requests for Information (FDA 3673)	1,535	1	1,535	0.25	384
807.41(a) <sup>3</sup> Identification of initial importers defined in 21 CFR 807.3(g) by foreign establishments (FDA 3673)	2,955	1	2,955	0.5	1,478
807.41(b) <sup>3</sup> Identification of other importers (defined in 21 CFR 807.3(x) and (y) that facilitate import by foreign establishments (FDA 3673)	3,234	1	3,234	0.5	1,617
Total					56,546

<sup>1</sup>Totals are rounded to the nearest whole number.

<sup>2</sup>One Time Burden – Firm only provides initially.

<sup>3</sup>Recurring Burden – Firm is required to review annually.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
807.25(d) <sup>2</sup> List of Officers, Directors & Partners	22,338	1	22,338	.25	5,585
807.26 <sup>2</sup> Labeling & Advertisements Available for Review	17,032	4	68,128	.5	34,064
Total					39,649

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>Recurring burden – Firm is required to keep records.

Our estimated burden for the information collection reflects an overall decrease of 17,637 hours and a corresponding decrease of 34,526 responses. Burden estimates are based on recent registration and listing information collected from establishments registering for the first time

(initial registration) and establishments re-registering. We attribute this adjustment to a decrease in the number of submissions we received over the last approval period.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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