

UNITED STATES FOOD & DRUG ADMINISTRATION

MEDICAL DEVICE REGISTRATION AND LISTING

OMB Control Number 0910-0625

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection implements Food and Drug Administration (FDA, us or we) statutes and regulations governing medical device registration and listing. Section 510 of the Federal Food, Drug, and Cosmetic Act governs registration of producers of devices, with implementing regulations at 21 CFR part 807. Domestic and foreign device establishments are required to submit registration and device listing information to FDA by electronic means rather than on paper forms, and in accordance with established submission schedules. Regulations in 21 CFR part 807, subparts A through D, identify who must register. The regulations also set forth format and content requirements and provide for a timed submission schedule, included the submission of updated information. To assist respondents with the information collection we maintain a website at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>, including a comment field. We utilize Form FDA 3673, now electronically formatted for web submission, to provide a uniform format for submission of required information.

We therefore request extension of OMB approval for information collection found in 21 CFR part 807, subparts A through D, and electronic Form FDA 3673, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collection to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution in order to effectively allocate FDA's field resources for inspections, and (3) the class of the device that determines the frequency of inspection. As a result, when complications occur with a particular device, all manufacturers of similar or related devices can be more readily identified. The information collection is also intended to mitigate bioterrorism threats and other public health emergencies.

The respondents to this information collection are private sector (both for profit and not for profit) 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.

3. Use of Improved Information Technology and Burden Reduction

The information collection is administered electronically using the FDA Unified Registration and Listing System (FURLS) to facilitate the electronic submittal of registration and listing information and to provide faster access to this information for both industry and FDA. This technology allows FDA to more effectively gather establishment registration information to help identify firms and the locations involved with the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices. We estimate 99% of respondents submit information electronically, reserving 1% for those requesting waiver from the electronic requirements.

Our Center for Devices and Radiological Health (CDRH) has developed step-by-step instructions explaining how firms submit registration and listing information electronically in FURLS to comply with the registration and listing requirements initially and annually. These step-by-step instructions can be found on our [website](https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#13) (<https://www.fda.gov/medical-devices/device-registration-and-listing/how-register-and-list#13>) in the tutorial section.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Information collection pertaining to the premarket notification of medical devices is governed by regulations in 21 CFR part 807, subpart E, and approved under OMB control no. 0910-0120.

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose undue burden on small entities, however the regulations provide for a waiver from submitting registration and listing information electronically. As instructed on our website, waiver requests should be submitted to the following address:

Food and Drug Administration
CDRH - Office of Compliance
Registration & Listing
10903 New Hampshire Avenue
Building 66 Room 2621
Silver Spring, MD 20993-0002

At the same time, FDA aids small business by providing guidance and information through our Center for Devices and Radiological Health (CDRH), Division of Industry and Consumer Education (DICE). DICE provides workshops and other technical and non-financial assistance to small manufacturers. The workshops make available publications and educational materials,

which include medical device establishment and listing requirements. The Division also maintains a toll-free “800” telephone number which firms may use to obtain regulatory compliance information. These efforts help to assure that the burden on small manufacturers is minimized.

6. Consequences of Collecting the Information Less Frequently

Failure to collect the required information as prescribed by statute would violate FDA’s mandate under the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information. This information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 8, 2022 (87 FR 7187). Although, no comments were submitted to the docket, one comment was received by e-mail regarding user interface with FURLS. The comment suggested that the two-step security process, PIN and PCN, seems redundant and unnecessary; when making payment, the commenter had difficulty finding the appropriate area within FURLS; and the comment noted that the many options on the payment site may contribute to confusion. While we have made no immediate changes to the information collection based on this comment, we will continue to consider such issues in making upgrades to the system as our limited resources permit.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected and to protect the privacy of the individuals. Although the information collection includes personally identifiable information (PII), it is collected in the context of the subject individuals’ professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted in FDA Form 3673, (Device Registration and Listing Module) is account identification, password, name, work address, email address, telephone number, fax telephone number, DUNS number, payment identification number (PIN), and payment confirmation number (PCN). Information collected via Form 3673 is maintained in a Privacy Act system of records as described in HHS/FDA System of Records Notice (SORN) 09-10-0021 for FDA’s

User Fee System. Individuals completing Form 3673 will complete it via the webpage where a notice will be displayed.

All information filed by a registrant is available for public inspection as required by 21 CFR 807.37. Information provided to, or obtained by, FDA is subject to release under the Freedom of Information Act (5 U.S.C. 552) and the implementing regulations contained in 21 CFR parts 20 and 21.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs⁴

12a. Annualized Hour Burden Estimate

SEE NEXT PAGE FOR BURDEN TABLES

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours ¹
807.20(a)(5) ² Initial Submittal of Manufacturer Information by Initial Importers	3673	5,736	1	5,736	1.75	10,038
807.20(a)(5) ³ Annual 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 & Listing		1	1	1	1	1
807.21(b) ² Initial Request for Waiver from Electronic Registration & Listing		1	1	1	1	1
807.22(a) ² Initial Registration & 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
807.22(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
807.26(e) ³ Labeling & Advertisement Submitted at FDA Request		71	1	71	1	71
807.34(a) ² Initial Registration & Listing when Electronic Filing Waiver Granted		1	1	1	1	1

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours ¹
807.34(a) ³ Annual Registration & 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 defined in 21 CFR 807.3(g) by foreign establishments	3673	12,983	1	12,983	0.5	6,492
807.41(b) ³ Identification of other importers (defined in 21 CFR 807.3(x) and (y) that facilitate import by foreign establishments	3673	12,983	1	12,983	0.5	6,492
Total burden						51,997

¹Totals are rounded to the nearest whole number.

²One Time Burden – Firm only provides initially.

³Recurring Burden – Firm is required to review annually.

Table 2.--Estimated Annual Recordkeeping Burden¹

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 & Partners	22,338	1	22,338	.25	5,585
807.26 ² Labeling & Advertisements Available for Review	17,032	4	68,128	.5	34,064
Total					39,649

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

²Recurring burden – Firm is required to keep records.

Burden estimates are based on recent registration and listing information collected from establishments registering for the first time (initial registration) and establishments re-registering.

The estimates for creation of new user accounts under § 807.21(a) are based on the number of newly registered owners and operators. An owner or operator only creates an account one time

when they register for the first time (initial registration). Once the account is created, the owner or operator uses the account as long as the establishment is registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered.

Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

While notification of transfer of ownership information is not currently required, our medical device registration and listing website (<https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>) communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

We estimate that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). We estimate that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

We estimate it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. We base this estimate on the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy. We estimate it will take respondents approximately 4 hours to establish the transfer of a 510(k) clearance.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify one importer and one person who imports or offers for import with readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. Upon review, they simply verify the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The

use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such lists current.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept for tax purposes.

12b. Annualized Cost Burden Estimate

We assume that the information collection will be completed by regulatory affairs professionals. We use, \$61.54, the U.S. Bureau of Labor Statistics’ May 2021 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm, median wage rate for a Lawyer (occupation code 23-1011) to calculate the burden for regulatory affairs professionals. To account for benefits and overhead, we double this value to \$123 (rounded).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Regulatory Affairs Professional	91,646	\$123	11,272,458

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The annualized cost to the federal government will be the cost of two full time FDA employees (FTEs). Based on a cost of \$297,561 per position (which is the agency’s projected average cost of an FTE in CDRH including their non-pay costs*), the estimated annual Federal cost is \$595,122.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2021, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,432 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last approval period. We have also consolidated the IC elements appearing at www.reginfo.gov, however we continue to provide a more detailed accounting of burden in our Tables at Question 12 of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.