**U.S Food and Drug Administration**
**Electronic Submission of Medical Device Registration and Listing**
**OMB Control No. 0910-0625**
**SUPPORTING STATEMENT**

## A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. On August 2, 2012, FDA amended its regulations governing medical device establishment registration and device listing. The revisions modified FDA's current regulations at part 807 (21 CFR part 807) to reflect recent statutory amendments to the device registration and listing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted on September 27, 2007, amended section 510 of the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In accordance with FDAAA, the agency launched FDA's Unified Registration and Listing System (FURLS), an internet-based registration and listing system. FDAAA requires electronic submission of device registration and listing information unless FDA grants a waiver request.

In addition, this rule facilitated FDA's collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). It also updated certain provisions in part 807 to improve the quality of registration and listing information available to FDA. FDA relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

To comply with the statutory deadline under the provisions of FDAAA for medical device establishment registration and device listing by electronic means, including waiver provisions, FDA initially obtained a six-month OMB approval of the collection of information requirements under the emergency processing provisions of the Paperwork Reduction Act (the PRA), and subsequently obtained a three year approval of these requirements under the same assigned OMB Control No. 0910-0625. With OMB approval of the collection of information requirements, FDA took several actions**: (1)** Developed an electronic form – "Device Registration and Listing Module," Form FDA 3673 and **(2)** developed and implemented the guidance "Guidance for Industry and FDA Staff- Implementation of Medical Device Establishments Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007." This guidance among other things explained the recent changes in the device registration and listing program and the process (instructions) for using FDA's Unified Registration and Listing Systems (FURLS), an Internet-based registration and listing system. This guidance has since been withdrawn. It is no longer published on the registration and listing website. In its place, we have created tutorials that provide step-by-step instructions explaining

the data that foreign and domestic establishments are required to submit to register their establishment and list their devices in FURLS.

We therefore request OMB continued approval of medical device registration and listing reporting and recordkeeping provisions found in 21 CFR Parts 807; and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA's electronic collection system was developed to facilitate the electronic submittal of registration and listing information and to provide faster access to this information for both industry and FDA. This system 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.

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution in order to effectively allocate FDA's field resources for these 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. In addition, knowing where devices are being made increases the Nation's ability to prepare for, and respond effectively to, 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 electronic submission of registration and listing information is a requirement of The Food and Drug Administration Amendments Act of 2007 (FDAAA) unless a waiver to electronic submission is granted. FDA's most recent experience is that over 99 percent of respondents will not request a waiver and will submit their information electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the collection of such information, and the only agency charged with the responsibility of regulating medical devices and establishments. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The registration and listing requirements do not fall disproportionately upon small businesses. The threshold assessment conducted for the regulation shows that no more than 22% of the anticipated annual impact of these regulations should be attributed to small business establishments. The FDA continues to pursue ways and means of reducing the reporting burden for both small and large medical device manufacturers and will continue to employ the latest technology for receipt of reports, consistent with the intent of the regulation and protection of the public health.

FDA aids small business in dealing with the requirements of the regulation by providing guidance and information through the Division of International and Consumer Education (DICE), and through the Registration and Risk Branch within the Center for Devices and Radiological Health. 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. Additionally, the Registration and Risk Branch has developed step-by-step instructions explaining how firms submit registration and listing information electronically to comply with the registration and listing requirements initially and annually. These step-by-step instructions can be found on our website in the tutorial section.

6. Consequences of Collecting the Information Less Frequently

The FD&C Act requires that a firm do the following:

1. Initial registration
2. Annual update of registration information
3. Initial device listing
4. Annual update of listing information
5. Update of listing information when a device with a classification name not currently listed by establishment occurs
6. Update of listing information when a device is discontinued
7. Update of registration information when an establishment moves or closes
8. Initial waiver request
9. Annual waiver from submitting information electronically request
10. Identification of Importers and persons who import or offer for import (for foreign establishments)
11. Identification of manufacturers (initial importers only)

A less frequent collection of information would not be responsive to the requirements of the FD&C Act or provide current information relative to device establishments and the listing and/or discontinuance of various medical device products they market. As discussed above, statutory requirements in the FD&C Act prevent this information from being collected less frequently.

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 December 4, 2018 (83 FR 62583). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA will not provide any payments or gifts to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted for FDA Form 3673, (Device Registration and Listing Module) now formatted for web submission, 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.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

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 information required in this information collection does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 93,798 hours annually. FDA estimates the burden of this collection of information as follows:

## 12a. Annualized Hour Burden Estimate

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 |
| 807.26(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 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 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 one time burden | | | | | | 14,976 |
| Total recurring burden | | | | | | 39,173 |

[1]Totals are rounded to the nearest whole number.
[2]One Time Burden – Firm only provides initially.
[3]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 & 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 |

[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.

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 recurring burden for the new data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on previous

data provided in this document. 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. When they review the importer information annually, 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 estimates for creation of new user accounts under § 807.21(a) are based on the number of owners or operators for calendar year 2017. An owner or operator only creates an account one time when they register for the first time (initial registration). Once the account is created, they use the owner or operator 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 transfer 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.

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.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate is based on the estimated hourly wage rate for a Regulatory Affairs Professional, $72.* Based on FDA's history with administrative detentions, FDA believes that the total estimated reporting and recordkeeping burden cost to industry for this information collection will be $6,753,456, which is the total number of estimated annual burden hours (93,798) multiplied by the wage rate of $72 per hour.

*The estimated wage rate is based on The Regulatory Affairs Professional Society (RAPS) average total compensation for all U.S.-based regulatory professionals at all levels, $150,422 per year (The Regulatory Affairs Professional Society (RAPS), "2016 Scope of Practice & Compensation Report for the Regulatory Profession," p. 11, downloaded from https://www.raps.org/careers/scope-of-practice-survey on 10/2/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Cost |
|---|---|---|---|
| Regulatory Affairs Professional | 93,798 | $72 | 6,753,456 |

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 $270,305 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 $540,610.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

The collection of information under these regulations will not be published for statistical use.

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

FDA is not seeking an exemption from the requirement to display the effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.