Electronic Submission of Medical Device Registration and Listing
0910-0625
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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.

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 a device 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.

More information about the waiver process is available on page 8 of FDA guidance entitled "Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007,"which is available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM185877.pdf.

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

One hundred percent of respondents will be businesses. 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 Device Registration and Listing 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.

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. Initial waiver request
8. Annual waiver from submitting information electronically request

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 October 27, 2015 (80 FR 65779). 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

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 72,597 hours annually. FDA estimates the burden of this collection of information as follows:

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	FDA Form Number	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	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	2,578
807.21(a)[3] Creation of electronic system account	3673	3,559	1	3,559	.5	1,780
807.21(b)[2] Annual Request for Waiver from Electronic Registration & Listing		14	1	14	1	14
807.21(b)[3] Initial Request for Waiver from Electronic Registration & Listing for		4	1	4	1	4
807.22(a)[3] Initial Registration & Listing	3673	3,539	1	3,539	0.5	1,770
807.22(b)(1)[3] Annual Registration	3673	20,355	1	20,355	0.75	15,266
807.22(b)(2)[3] Other updates of Registration	3673	4,176	1	4,176	0.5	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 & Advertisement Submitted at FDA Request		71	1	71	1	71
807.34(a)[2] Initial Registration & Listing when Electronic Filing Waiver Granted		14	1	14	1	14

807.34(a)[3] Annual Registration & Listing when Electronic Filing Waiver granted		4	1	4	1	4
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	10,329	1	10,329	0.5	5,165
807.41(b)[3] Identification of other parties that facilitate import by foreign establishments	3673	10,329	1	10,329	0.5	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	No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
807.25(d)[2] List of Officers, Directors & Partners	23,806	1	23,806	.25	5,952
807.26[2] Labeling & Advertisements Available for Review	11,746	4	46,984	.5	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.

Burden estimates are based on recent experience with the existing medical device registration and listing program, electronic system operating experience since October 2007, and the economic analysis provided by ERG for the final rule. 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 the ERG memo. This report stated that foreign establishments would typically be identifying one or two importers and one or two persons who import or offer for import with readily available contact information.

The estimates for creation of new user accounts under § 807.21(a) are based on the number of owners or operators, and experience in account creation using the existing FURLS for medical device registration and listing since October 2007. At that time, the existing owner operator information from the legacy database was migrated to the new system thereby automatically creating accounts for those owners. The estimates included in this submission are for the recurring years only and assume a similar increase in the number of new owner or operator numbers as were created at the time of the final rule.

The estimate for § 807.25(d) in table 3 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

Table 3 summarizes the projected quantified impacts of the elimination of registration and listing exemptions for contract manufacturers and sterilizers who do not commercially distribute devices. The total annual costs are $1,350,047. Foreign establishments would face an additional annual burden of $138,000 due to the loss of the exemptions from registration and listing requirements relating to devices entering a foreign trade zone that are later re-exported without having entered U.S. commerce and devices that are imported into the United States under section 801(d)(3) of the FD&C Act. Table 4 summarizes the transfer costs of $2.14 million in additional user fees paid by contract manufacturers and sterilizers. Table 5 summarizes the estimated reporting and recordkeeping burden for electronic registration and listing under the rule. The total annualized cost burden associated with the information collection is $7,873,023 ($1,350,047 projected impact cost + $138,000 projected foreign establishments impact cost + $2,140,000 transfer costs + $4,244,976).

Table 3.--Projected Impacts of the Rule

Establishment Category	No. of Affected Establishments/ Devices	Incremental Time	Cost per Hour[1]	Total Annual Cost[3]
Requests for a Waiver from Submitting Information Electronically	14 establishments	1 hr	$41	$574
Foreign establishments shipping to United States under import-for-export and to foreign trade zones	none [2]	2.5 hrs	$41	$0[2]
Elimination of Exemptions for Contract Manufacturers	2,772 devices, 1,042 establishments	2.5 hrs	$41	$284,000
Elimination of Exemptions for Contract Sterilizers	543 devices, 116 establishments	2.5 hrs	$41	$56,000
Initial Importers	8,594 establishments for 80,000 devices	1.9	$41	$669,473
All other	negligible	--	--	negligible[3]
Total	1,178 establishments 3,315 devices	--	--	$1,350,047

[1] Average hourly wage for medical equipment and supplies compliance officer, adjusted for benefits.
[2] Provision would not be expected to affect U.S. establishments. An estimated 1,344 foreign establishments would face additional annual costs of $138,000.
[3] Estimated incremental time costs are offset by incremental time savings.

Table 4.—Economic Transfers Associated with the Rule

From	To	Description	Cost per Entity	Total Cost
1,042 Contract Manufacturers and 116 Contract Sterilizers	U.S. Government	Establishment Registration Fees	$1,851	$2.14 million

Table 5.— Reporting and Recordkeeping Costs

Type of Respondent	Total Reporting and Recordkeeping Burden Hours	Cost per Hour	Total Cost
Regulatory Affairs	72,597	$41	2,976,477

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

FDA the annualized cost to the federal government will be the cost of two full time FDA employees (FTEs). This amounts to a total of $566,974, based on a cost of $283,487 per position (which is the agency's projected average cost of an FTE including benefits*).

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to the estimated information collection burden.

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.