Electronic Submission of Medical Device Registration and Listing
0910-0625-Revision
Final Rule RIN (0910-AF88)
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) amended its regulations governing medical device establishment registration and device listing. The revisions modify 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) that were made in the Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted on September 27, 2007. FDAAA 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 facilitates 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 updates 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.

Transition Process from Paper to Electronic Submission
The information collection requirements for paper submissions were approved under the assigned OMB control number 0910-0387 with the associated Forms FDA 2891, 2891a and 2892. Upon approval of electronic registration and listing information collection requirements under FDAAA, FDA: **(1)** Replaced the paper forms FDA 2891, 2891a and 2892 with the electronic data collection instrument, Form FDA 3673**; (2)** revised the collection of information 0910-0387 for paper submissions to include only non registration and listing paperwork requirement, thereby reducing the annual reporting burden requirements (the registration and listing requirements under FDAAA were updated as a revision to the collection 0910-0625); **(3)** following notice in a June 17, 2007 letter to firms, shut down the manual data entry system on September 15, 2007, and began using the new electronic system on October 1,2007; and **(4)** sent each firm a letter on October 1, 2007, providing account and password information for the new system. FDA intends to discontinue 0910-0387 "Additional Listing Information for Medical Device Registration and Listing." The burden described in 0910-0387 is covered in 0910-0625. Please note the following:

1. 0910-0387 currently accounts for 2,250 respondents for 807.31(d)(2) (now 807.26(d)(2) as redesignated by the eRegistration & Listing rule). When the contents of the historical file are physically located in more than one establishment, but no joint ownership and control exists, the registered establishment must provide FDA a letter authorizing the other establishment to maintain the file. This line item in the burden table accounts for the burden of the letters. However, we rarely, if ever, receive these letters and we therefore estimate that there will be 1 respondent and an annual burden of 1 hour going forward. Sec. 807.26(d)(2) is not specifically set out in 0910-0625. However, the existing program has not changed.
2. The burden estimates for 807.26 in 0910-0625 were derived from the ERG Report done for the proposed eRegistration & Listing rule and subsequently updated with the actual registration and listing data in FURLS at the final rule stage. The estimates listed in 0910-0625 are therefore more accurate and up-to-date than those listed in 0910-0387, which were based on FY 2010 data and conversations with industry and trade association representatives.

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 (approved under OMB Control Number 0910-0625) is that over 99% 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm185871.htm

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 this 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 Small Manufacturers, International and Consumer Assistance (DSMICA), and through the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA 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:

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

Existing ICR 0910-0625 was published for comment on 11/3/11 (76 FR 68195). The proposed rule published on 3/26/10 (75 FR 14510) served as the Notice for comment.

FDA continually seeks input from industry representatives as well as trade associations concerning registration and listing policies and procedures. Over the last three years, FDA has sent annual letters explaining how to avoid making the most common errors when completing the electronic forms and informing establishments of any proposed regulatory changes. In addition, the Registration and Listing website is updated routinely and FDA staff gives presentations about pertinent topics at workshops with industry. FDA maintains an email account where questions, comments and concerns can be submitted. Comments can also be submitted to FDA via its web site.

9 Explanation of Any Payment or Gift to Respondents

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

10Assurance 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.

11Justification 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 72,625 hours annually.

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table I. -- 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	3673	1,615	1	1,615	0.5	808

of US Agent Information						
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 II. -- 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.

The currently approved reporting and recordkeeping burden for electronic registration and listing under OMB No. 0910- 0625 is 72,625. The estimated reporting and recordkeeping burden for electronic registration and listing under the rule is 99,470 hours, an increase of 26,845 hours. This increase is due to the incremental increase of respondents no longer exempt from these requirements weighed against the change in reporting requirements for all owner operators and the decrease in the overall number of device establishments that have registered since OMB No. 0910-0625 was published.

The estimate would have been 16,790 burden hours larger if FURLS had not provided a more accurate estimate of the number of establishments.

The entire increase can be attributed to the additional filers and additional information. The estimate of the number of establishments registering and listing went down with the advent of FURLS, because there were actually about 10,000 less establishments registration and listing then had been previously estimated.

If FDA did not have the more accurate estimate from FURLS, instead of estimating 59, 242 annual responses we would estimate there would have been 69, 242 annual responses. [59,242 + 10,000 = 69,242]. The total estimated burden would have increased by 16,790 hours to 116,260. [(99,470 X 69,242)÷59,242 = 116, 260 then 116,260 – 99,470 = 16, 790] The program increase would have increased to 43,635 hours (26,845 + 16,790 = 43,635).

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. The changes to the actual data collected are, with one exception, very minor. We are assuming that it will take approximately the same amount of time to enter the data online using FURLS as it does to use the portable document format (PDF)-enabled forms that had been used for initial establishment registration prior to FURLS becoming operational in October 2007. Any additional burden associated with creating and using the Web-based system accounts (as shown in table 1 of this document under 807.21(a)) should be offset by the elimination of the need to re-enter identifying information concerning the establishment or product every time registration or listing information is updated, which was the case when updating such information using the PDF-enabled forms.

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 current 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, therefore, are for the recurring years only and assume a similar increase in the number of new owner or operator numbers as were created in the most recent complete fiscal year, FY 2011.

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.

The requirements shown in table 2 for § 807.26 (renumbered from § 807.31), have not changed based on this revision to the registration and listing regulations. They reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records when requested by FDA. They are based on experience FDA has had with the existing regulation.

This rule also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 807.35(b) have been approved under OMB control number 0910-0052. This rule is not going to impact the burden in 0910-0052 that is already accounted for in that information collection."

12b. Annualized Cost Burden Estimate

Table III 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 IV summarizes the transfer costs of $2.14 million in additional user fees paid by contract manufacturers and sterilizers. Table V summarizes the estimated reporting and recordkeeping burden for electronic registration and listing under the rule. The total annualized cost burden associated with this rule 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 IV.—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 V.— 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

13Estimates 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.

14Annualized Cost to the Federal Government

FDA anticipates that the annualized cost to the federal government will be the cost of two full time FDA employees. FDA estimates one full time employee cost is $104,000 per year, with a total cost of $208,000.

15Explanation for Program Changes or Adjustments

There is a program change increase of 26,845 hours and the annual responses have increased by 59,242. The current estimated burden approved under OMB control No. 0910-0625 for electronic registration and listing is 72,625 hrs. For this rule, the estimated burden is 99,470 hrs an increase of 26,845 hours. FDA attributes the increase in burden hours to the more accurate estimates from FURLS and the increase in burden from requiring (1) initial importers to identify manufacturers by product, (2) foreign manufacturers identifying their importers, and (3) contract manufacturers and sterilizers that do not put their devices into commercial distribution to register and list.

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.