Implementation of Sections 222, 223, and 224 of the
Food and Drug Amendments Act of 2007
0910-0625-Revision
RIN (0910-AF88)
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is proposing to amend its regulations governing medical device establishment registration and device listing. The proposed revisions would 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). 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 proposal would facilitate 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 would update 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.

This collection of information collection is not related to the American Recovery and Reinvestment Act of 2009.

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.

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

100% 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 percent 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) initially register once; (2) update the registration annually; (3) initially list a device when it is placed into commercial distribution (once); and (4) update the listing whenever there is a change or discontinued device (occasionally). For those firms requesting waivers, each must re-request a waiver annually. 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 10/1/08 (73 FR 57106) and 12//12/08 (73 FR 75723). This proposed rule will service 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.

12Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 103,536 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)[3]	3,673	800	1	800	0.75	600
807.21(a)[3]	3,673	125	1	125	0.5	63
807.21(b)[2]		20	1	20	1	20
807.21(b)[3]		1	1	1	1	1
807.22(a)[3]	3,673	2,566	1	2,566	0.5	1283
807.22(b)(1)[3]	3,673	29,100	1	29,100	0.75	21825
807.22(b)(2)[3]	3,673	3,000	1	3,000	0.5	1500
807.22(b)(3)[3]	3,673	24,870	1	24,870	1	24870
807.26(e)[3]		100	1	100	1	100
807.34(a)[2]		20	1	20	1	20
807.34(a)[3]		1	1	1	1	1
807.40(b)(2)[3]	3,673	50	1	50	0.5	25
807.40(b)(3)[3]	3,673	1,836	1	1,836	0.25	459
807.41(a)[3]	3,673	11,348	1	11,348	0.5	5674
807.41(b)[3]	3,673	11,348	1	11,348	0.5	5674
Total one time burden						40
Total recurring burden						62075

[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]	33,490	1	33,490	.25	8,373
807.26[2]	16,524	4	66,096	.5	33,048
Total					41,421

[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 71,319. The estimated reporting and recordkeeping burden for electronic registration and listing under the proposed rule is 103,536 hours, an increase of 32,217 hours. This increase is due to an under estimate of the original burden estimate for 0910-0625 and the incremental increase of respondents no longer exempt from these requirements.

Burden estimates are based on recent experience with the existing medical device registration and listing program 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 Food Facility Registration. The estimates for the recurring years assume a similar increase in the number of new owner or operator numbers as were created in FY 2006.
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 3 for proposed § 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 proposed 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 $340,000. 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 proposed rule. The total annualized cost burden associated with this proposed rule is $6,862,976 ($340,000 projected impact cost + $138,000 projected foreign establishments impact cost + $2,140,000 transfer costs + $4,244,976).

Table III.-- Projected Impacts of the Proposed 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	20 establishments	1 hr	$41	$820
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
All other	negligible	--	--	negligible[3]
Total	1,178 establishments 3,315 devices	--	--	$340,000

[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 IV.—Economic Transfers Associated with the Proposed 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	103,536	$41	4,244,976

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 federal government will incur the following costs:

Staff Costs

Total annual cost to the Federal Government = $1,528,775

Full time Equivalents = 2

Annual Cost per FTE=$104,000

Annual Cost = $208,000

15Explanation for Program Changes or Adjustments

There is a program change increase of 32,217 hours due to agency discretion. The current estimated burden approved under OMB control No. 0910-0625 for electronic registration and listing is 71,319 hrs. For this proposal, the estimated burden is 103,536 hrs an increase of 32, 217 hrs. This increase is due to an under estimate of the original burden estimate approved under the emergency processing provisions of the PRA and the incremental increase of respondents no longer exempt from these requirements.

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.