Electronic Submission of Medical Device Registration and Listing~~Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007~~

OMB Control No. 0910-0625

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This information collection request covers the reporting and recordkeeping provisions associated with FDA's implementation of ~~S~~sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which require that device establishment registrations and listings under section 21 U.S.C. 360(p) (including the submission of updated information) be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. Sections 222 and 223 of the FDAAA amend sections 510(b) and 510(j)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require domestic and foreign establishments to annually register and list between October 1 and December 31 of each year. In addition, section 222 of the FDAAA amends section 510(i)(1) of the FD&C Act to require foreign establishments to register upon first engaging in the device activity described under the statute and annually between October 1 and December 31 of each year.

Under the FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the electronic system (FDA Form No. 3673). Owners or operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of the FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when "the use of electronic means is not reasonable for the person requesting such waiver."

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

2. Purpose and Use of the Information Collection

The information collected by electronic registration and listing will aid FDA in protecting the public from potentially hazardous devices, as well as devices with confirmed hazards. This information is used to identify geographic distribution in order to effectively allocate FDA field resources for inspections and to identify the class of the device that determines inspection frequency. In addition, when complications occur with a particular device or component, manufacturers of similar or related devices can easily be identified. If the firms did not submit this information, they would not be inspected regularly and defective devices could remain on the market, presenting potential life-threatening situations to the public.

A person is allowed to request a waiver from the requirement of electronically registering and listing when it is not reasonable for the requestor to do so. FDA will use the information collected in a waiver request to determine whether the requestor's circumstances and justification establish that electronic registration

and listing is not reasonable. If the waiver is granted, the requestor will be allowed to register and list by non-electronic means.

3. Use of Improved Information Technology and Burden Reduction

There are no technical or legal obstacles to the collection of this information. The registration and listing process is now a paperless process, both for initial and updated submissions, which also permits real-time updates. FDA has eliminated all paper forms (FDA forms 2891, 2891a, and 2892) and now uses the FDA Unified Registration and Listing System (FURLS). FDA estimates that 99% of respondents will report electronically. Although some firms may not subscribe to an Internet service provider, FDA believes ready access is available through multiple channels: local libraries, FDA district offices, and commercial services ~~such as Fed Ex Kinko's~~. Other federal agencies, notably the Securities and Exchange Commission, the Federal Communications Commission, and the Internal Revenue Service have already instituted electronic filing requirements that specifically exclude parallel paper submissions. The 2007 legislation, FDAAA does permit FDA to waive the requirement to electronically register and list under certain circumstances; see Section 510 of the FD& C Act, as amended by Section 224 of the FDAAA. FDA estimates that 1% of these establishments will not acquire access to the Internet.

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 requirements set forth in sections 222, 223, and 224 of the FDAAA 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 that 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

~~(1) initially register once; (2) update the registration annually; (3) initially list a device when it is placed into commercial distribution (assuming initial registration); and (4) update the listing whenever there is a change or discontinued device. 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.

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

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 November 3, 2011 (76 FR 68195), FDA published a 60-day notice requesting comments on the information collection. FDA received no comments.

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 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. Replies are usually sent within 2 working days of receipt. Comments can also be submitted to FDA via its website.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

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.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimate of burden for this collection of information is shown in the following tables:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section from Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) ~~of the 2007 Amendments~~	FDA Form No.	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Update of Registration Information (Section 222)[2]	3673	21,254	1	21,254	0.75	15,941
Initial Registration (Section 222)[1]	3673	2,162	1	2,162	0.50	1,081
Annual Registration of Foreign Establishments (Section 222)[2]	3673	8,067	1	8,067	1	8,067
Annual Update of Changes to US Agent Information (Section 222)[2]	3673	1,305	1	1,305	0.25	326
Annual Update of Listing Information (Section 223)[2]	3673	17,750	1	17,750	1	17,750
Initial Waiver Request (Section 224 ~~(waiver request)~~)[1]	3673	14	1	14	1	14
Annual Waiver Request (Section 224 ~~(waiver request)~~)[2]	3673	1	1	1	2	2
Total						43,181

[1]One time burden (Annually Registering).
[2]Annual recurring burden.

The estimates in Table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form

3673 does not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishment owner/operators, for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a device establishment's owner/operator is required to register and list, they would need only to have access to a computer, Internet and an e-mail address for registration and listing by electronic means, the agency did not anticipate receipt of a large number of requests for waivers. From the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded. The number of waiver requests received through fiscal year 2011 have remained consistently less than 1 percent.

Based on information taken from our databases, FDA estimates that there are 21,254 owner/operators who collectively register a total of 24,000 device establishments. The number of respondents listed for section 222 of FDAAA in Table 1 of this document is 21,254, which corresponds to the number of owner/operators who annually register. In addition, FDA estimates that 3,504 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in Table 1 of this document for section 223 of FDAAA is 17,750, which corresponds to the number of owner/operators who annually list one or more devices (21,254 - 3,504 = 17,750).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than 1 percent of the 24,000 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 14 requests (24,000 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,162 new establishments each year. Of the 2,162 new registrants each year, we assume that less than 1 percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 14 waiver requests, which could increase by only one additional request each year.

Based on the number of owner operators of foreign establishments reflected in our current database, approximately 8,067 owner operators will spend an hour annually identifying the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer of the establishment's devices that is known to the foreign establishment.

Also based on the current number of owner/operators in the FDA database, we estimate that approximately 1,305 owner operators will spend .25 hours each year to identify changes in their U.S. agent's name, address, or phone number to FDA.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section from Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) ~~of the 2007 Amendments~~	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Requirement to keep a List of Officers, Directors and Partners Available (Section 222)[1]	23,806	1	23,806	0.25	5,952
Requirement to keep Labeling and Advertisements and other Promotional Material Available for Review (Section 223)[1]	11,746	4	46,984	0.50	23,492
Total					29,444

[1] Recurring burden.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in Table 2 of this document complies with 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 upon request from FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

12b. Annualized Cost Burden Estimate

The following is the estimated annual burden costs for medical device establishments to meet the requirements of sections 222, 223, and 224 of the FDAAA. Assuming a burden of 43,181 hours and a labor cost of $27 per hour including benefits, the cost for all affected establishments would be $ 1,165,887 ($27 per hour x 43,181 hours). This annual rate was determined by the Agency's current estimates of staff

expenses.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Healthcare professionals	29,444	$55	$161,942.00
Recordkeepers	43,181	$27	$1,165,887.00
Total			$1,327,829.00

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

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

14. Annualized 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

15. Explanation for Program Changes or Adjustments

There has been an adjustment in the burden hours and annual responses for this collection. The burden for this collection has increased by 1,306 hours and the annual responses have decreased by 8,420 responses. The new total is 72,625 burden hours and 50,553 annual responses. FDA attributes the increase in burden to the additional information that must be submitted to comply with FDAAA. FDA attributes the decrease in responses to more accurate estimates. Prior to the electronic system, registrants were not deleted from they rolls unless an FDA District Office confirmed that the registrant was no longer in business. Under the system currently in place, potential registrants were notified that they must confirm their registrations or they would be deleted from the system.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

FDA is not requesting an exception to Certification for the Paperwork Reduction Act Submissions.