SUPPORTING STATEMENT
FOR
Additional Listing Information for Medical Device Registration and Listing
21 CFR PART 807.31
OMB No. 0910-0387

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of approval of the information collection requirements in 21 CFR 807.31. The Food and Drug Administration Amendments Act of 2007 (FDAAA), enacted September 27, 2007 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. While the 2007 Amendments provided for an October 1, 2007 effective date, the reporting and recordkeeping burdens associated with additional listing information address non-electronic submissions. The reporting and recordkeeping required by non-electronic means, which are described below, are set forth in 21 CFR § 807.31- Additional listing information.

The regulations for registration and listing are in 21 CFR Part 807.31.

21 CFR 807.31(e) – Reporting

States that each owner or operator must be prepared to submit to FDA, upon specific request, copies of all labeling and advertising, statements of basis that the device is not a restricted device or a drug, and the name of distributors for whom a device has been manufactured under a label other than its own.

21 CFR 807.31(a-d) – Recordkeeping

Requires each owner or operator to maintain an historical file containing the labeling and advertisements in use on the date of initial listing and in use after October 10, 1978, but before the date of initial listing. In addition, they shall maintain in the historical file any labeling or advertisements in which materials change has been made anytime after the initial listing. These files must be maintained for a period of 3 years after the date of the last shipment of a discontinued device by an owner or operator and made available when requested by FDA.

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

2. Purpose and Use of the Information

This information collection is necessary for the FDA to assure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The information will aid FDA in protecting the public from potentially hazardous devices, as well as devices with confirmed hazards. FDA analyzes the information as it is submitted, checking for problems in individual reports, and analyzing accumulated data to determine trends. Results of these analyses are utilized to determine if an FDA action is necessary, and if so, what action is appropriate.

FDA is required to inspect manufacturers of certain medical devices to ensure that the devices are manufactured in accordance with good manufacturing practices. This information is used to identify geographic distribution in order to effectively allocate FDA field resources for these inspections and to identify the class of the device that determines the 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.

3. Use of 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). 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 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 expects, therefore, 100% of respondents will submit the information in written form.

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 Business or Other Small Entities

The requirements set forth in this regulation 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 Federal Food, Drug, and Cosmetic 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; and (4) update the listing whenever there is a change or discontinued device. 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 Agency

In accordance with 5 CFR 1320.8(d), on December 7, 2010 (75 FR 76008), a 60-day notice for public comment was published in the Federal Register. No comments were received.

FDA continually seeks input from industry representatives as well as trade associations concerning registration and listing policies and procedures. The Registration and Listing website is updated routinely and FDA staff give presentations about pertinent topics at workshops with industry. FDA maintains an e-mail account where questions, comments, and concerns can be submitted. Replies are usually sent out 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 Respondent

Confidentiality of information submitted to FDA is governed by the provisions of 21 CFR 807.95. All registration and some listing data collected is available upon request under the Federal Freedom of Information Act, subject to FDA's implementing regulations, 21 CFR Part 20, Public Information. In addition, all information filed by a registrant is available for public inspection as required by 21 CFR 807.37.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The following is the estimated annual burden hours for medical device establishments to comply with the information collection requirements imposed by this regulation.

Table 1. – Estimated Annual Reporting Burden

21 CFR Section	Number of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
807.31(d)(2)	2,250	1	2,250	.5	1,125
807.31(e)	22,500	1	22,500	.5	11,250
Total Hours					12,375

Table 2. – Estimated Annual Recordkeeping Burden

21 CFR Section	Number of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
807.31(a-c)	22,500	4	90,000	0.50	45,000

The respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, e.g., establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution. FDA bases the estimates on FY10 data from current database systems and on conversations with industry and trade association representatives.

12b. Annualized Cost Burden Estimate

The annual reporting cost to respondents for registering establishments and listing devices is $680,625. This figured was derived by multiplying the total reporting burden hours from Table 1 by an hourly rate of $55. This hourly rate is based on 2,080 annual work hours and an annual salary rate of $116,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. and 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	12,375	$55	$680,625
Recordkeepers	45,000	$32	$1,440,000
Total			$2,120,625.00

Using FY10 data, FDA estimates that recordkeeping (Table 2 above) costs for respondents is $1,440,000. This figure was determined by multiplying the total number of hours estimated for recordkeeping (45,000) by $32.00. Historical submissions, trend analysis, and estimates for annual cost of living increases determined the hourly rate.

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

There are no additional costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA anticipates that the total annual cost to the federal government is $996,000. This cost was calculated by multiplying the number of full time employees (6) by the annual loaded salary cost of $696,000. Also, because the agency contracts secretarial assistance and an 8A contractor to process all registration and listing submissions, there is an additional $300,000 in contract costs associated with the information collection requirements.

15. Explanation for Program Changes or Adjustments

The number of both reporting and recordkeeping burden hours increased since the last approval of the information collection. FDA attributes this increase to an overall increase in firms registering and listing under current agency regulations.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for 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

There are no exceptions to Item 19 of OMB Form 83-I.