SUPPORTING STATEMENT
FOR
Medical Device Registration and Listing
21 CFR PARTS 807.22 & 807.31
OMB No. 0910-0387

A. JUSTIFICATION

The Food and Drug Administration (FDA) is requesting an extension of approval of the information collection requirements in 21 CFR Parts 807.22 through 807.31 and 807.40 (Attachment 1). This section describes the procedures for domestic and foreign device establishments who must register and submit a device list. FDA has modified FDA forms 2891, 2891(a), and 2892 by clarifying questions and improving the overall format of the forms. FDA had observed that certain mistakes were occurring frequently, and many of the revisions to the forms were implemented as an effort to reduce these common types of errors. An increase in the accuracy of the information submitted on the forms will result in fewer communications cycles with industry and will reduce the overall reporting and recordkeeping burden on FDA's stakeholders. In addition, the redesign of Form 2892 will actually result in a reduction of the number of device listing forms that a stakeholder will need to submit.

1. Circumstances Making the Collection of Information Necessary

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Attachment 2) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with the Food and Drug Administration (FDA). This is accomplished by completing FDA Form 2891, "Registration of Device Establishments" and FDA Form 2892 "Medical Device Listing." (Attachment 3) The term "device" is defined in section 201(h) of the FD&C Act and includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act (42 U.S.C. 262). The FDA Modernization Act of 1997 (FDAMA) added a requirement for foreign establishments to appoint a United States Agent and submit the information to FDA as part of its initial and updated registration information. Rather than create an additional form for the submission of this information, FDA has chosen to add the collection of this information to FDA Form 2891.

The regulations for registration and listing are in 21 CFR Parts 807.22 through 807.31, and 807.40.

21 CFR 807.22(a) - REPORTING

Describes how and where to register establishments and list devices. This section explains that the establishment should first register on Form FDA-2891 (Registration of Device Establishment) and subsequent annual registration shall be accomplished on form FDA-2891a (Annual Registration of Device Establishment). FDA will furnish Form 2891a to establishments whose registration for that year was validated under 21 CFR 807.35(a). The completed form shall be mailed to the FDA 30 days after receipt. Additional updating is required when changes occur in ownership, establishment name, official correspondent, or addresses. FDA must be notified in writing within 30 days of such changes. In the past, a letter had to be submitted which identified the establishment and described the changes. Establishments often fail to submit a piece(s) of required information when sending a letter informing FDA of changes. Because of problems receiving all of the necessary information, FDA has chosen to use Form 2891 as the method by which all changes will be submitted.

21 CFR 807.22(b) - REPORTING

Specifies that the initial listing of devices and subsequent June and December updating shall be on form FDA-2892 (Medical Device Listing). Forms are obtainable upon request from FDA, and a separate form FDA-2892 shall be submitted to list multiple devices for each establishment registered with FDA. This change in process is expected to reduce the number of device listing forms submitted by a stakeholder. For example, currently if the establishment needs to list two different classified devices, they have to submit two forms. FDA's new process now only requires a single form that lists both devices. If variations in size, package shape, color, or composition exist, the device should be considered to be one device provided the variation does not change the function or intended use of the device.

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 - 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.

21 CFR 807.40 - REPORTING

Describes the role of the United States (US) Agent. The US Agent must reside or have a physical place of business in the Untied States. States that each foreign establishment must submit US agent information as part of its initial and updated registration process. In an effort to simplify this reporting requirement, the US Agent data is now a part of Form 2891 and 2891(a).

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.

FDA continues to evaluate current program efficiency and provide recommendations on possible streamlining of the program. These initiatives include not only programmatic changes, but processing and data submission enhancements as well.

One of the projects is the ability for industry to submit all registration and listing data electronically via the Internet. The registration and listing process will be converted to a paperless process, both for initial and updated submissions, and will permit real-time updates for the first time FDA will eliminate all paper forms (FDA forms 2891, 2891a, and 2892) and use 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 proposed regulation will solicit comments on the need for a "hardship exemption" for firms that do not have a personal computer capable of connecting to the Internet or the alternative FDA WWW server.

While this paperless process is being developed, FDA allows medical device establishments to use a PDF enabled version of the forms FDA 2891 and 2892. FDA internal data files on registration and listing have been converted to online systems to reduce the processing burden and to provide information in a more timely manner. FDA makes nearly all registration and listing data available to the public via the Internet. In addition, FDA provides a web based mechanism that allows the public to search for device classification names and other information. All of this information is updated monthly.

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), October 29, 2004 (69 FR 63156), a 60-day notice for public comment (Attachment 4) was published in the Federal Register. No comments were received from the public.

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 give 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 out within 2 working days of receipt. Comments can also be submitted to FDA via their web site.

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. Estimate of Hour Burden Including Annualized Hourly Costs

The following is the estimated annual burden hours for medical device establishments to report in compliance with the provisions imposed by this regulation.

The annual reporting cost to respondents for registering establishments and listing devices is $472,500. This figured was derived by multiplying the total reporting burden hours from Table 1B by an hourly rate of $50. This hourly rate is based on a 2,080 annual work hours and at an annual salary rate of $104,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses.

FDA bases the estimates on FY03 data from current systems and on conversations with industry and trade association representatives, and from internal review of the documents listed in the below table.

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

Table 1A. --Estimated Year 1 Annual Reporting Burden

FOR INFORMATION PURPOSES ONLY

21 CFR Section	FDA Form	Number of Respondents	Annual Frequency of Response	Total Annual Responses	Hours Per Response	Total Hours
807.22(a) & 807.40	Form 2891 Registration of Device Establishment—initial and updates	2,900	1	2,900	.25	725
807.22(b)	Form 2892 Medical Device Listing –initial and updates	4,400	1	4,400	.50	2,200
807.22(a) & 807.40	Form 2891 (a) Annual Registration of Device Establishments – registration update	25,100	1	25,100	.25	6,275
807.31(e)		200	1	200	.50	100
Total Year 1 Burden Hours						9,300

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

Table 1B. --Estimated Subsequent Years Annual Reporting Burden

21 CFR Section	FDA Form	Number of Respondents	Annual Frequency of Response	Total Annual Responses	Hours Per Response	Total Hours
807.22(a) & 807.40	Form 2891 Registration of Device Establishment—initial and updates	3,100	1	3,100	.25	775
807.22(b)	Form 2892 Device Listing – initial and updates	4,600	1	4,600	.50	2,300
807.22(a) & 807.40	Annual Registration of Device Establishments – registration update	25,100	1	25,100	.25	6,275
807.31(e)		200	1	200	.50	100
Total Year 2&3 Burden Hours						9,450

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

Using FY03 data, FDA estimates that recordkeeping (Table 2 below) costs for respondents is $923,400. This figure was determined by multiplying the total number of hours estimated for recordkeeping (32,400) by $28.50. Historical submissions, trend analysis and estimates for annual cost of living increases at 3% determined the hourly rate.

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	16,200	4	64,800	.50	32,400
Total Burden Hours					32,400

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

There are no additional 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 = 6
Annual Cost per FTE=$104,000
Annual Cost = $624,400

Contract Costs = $ 904,775 - We currently pay for the temporary secretarial assistance and the services of an 8A contractor to process all registration and listing submissions.

15. Explanation for Program Changes or Adjustments

The explanation for adjustments from the previous approval is:

- The number of respondents has changed. We report numbers based on the current findings from our automated database which provides us with submission numbers and rates. Based on FY03 data, the number of active registered establishments has increased. The explanation for this increase is that 1) better communication with industry regarding the need for firms to register and 2) due to changes in the regulations foreign firms must now register. This change was not taken into consideration when the previous supporting statement was developed. The number of listing forms submitted to FDA is shown to increase only slightly. There would have been a more dramatic increase in the number of forms if FDA had not revamped the form. The new form allows for the submission of listing information by establishment rather than by product code. It is projected that there will be 35 percent fewer forms submitted using this new format. This change in the form will make reporting listing information more efficient for industry and easier for FDA to process. Burden for this information collection does decrease by 24,611 hours, which is the previous burden of 66,461 hours minus the current burden of 41,850 hours.

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

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

19. Certification for Paperwork Reduction Act Submissions

No exceptions have been identified.

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.

LIST OF ATTACHMENTS:

Attachment 1 - Code of Federal Regulations (21 CFR 807, Subpart B, Parts 807.20 through 807.31, and 807.40)

Attachment 2 - Federal Food, Drug, and Cosmetic Act, Section 510

Attachment 3 - Medical Device Registration and Listing Forms FDA 2891, 2891a, and 2892

Attachment 4 - Federal Register 60 day Notice