SUPPORTING STATEMENT
FOR
Implementation of Sections 222, 223, and 224
of the Food and Drug Administration Amendments Act of 2007

. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Effective September 27, 2007, sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) 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. FDA expects 20,000 to 30,000 establishments to begin registering electronically at that time. These establishments must have available an opportunity to request waivers. Thus, emergency approval of this request is necessary to implement the statute.

Sections 222 and 223 of the FDAAA amend sections 510(b) and 510(j)(2) of the 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 new 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."

2. Purpose and Use of the Information

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 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.

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 Information Technology and Burden Reduction

There are no technical or legal obstacles to the collection of this information.

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 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 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; 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 Agency

This emergency Federal Register notice will request comments from the public. (Attachment 2).

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 its 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

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 estimates in Table 1 below 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 will not differ significantly from the time needed to fill in the forms because the information required is essentially identical.

In addition, under section 224 of the FDAAA, parties for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a party required to register and list would only need to have access to a computer, Internet access, and an email address to register and list by electronic means, we do not anticipate that we will receive many requests for waivers.

The Center for Food Safety and Nutrition has been using FDA Unified Registration and Listing System (FURLS) for the electronic registration of food establishments for about two years. As of September 2006, over 98% of food establishments were voluntarily submitting their registration information electronically. We expect FURLS usage for device registration and listing would be at least as high and estimate that no more than two percent of device establishments would submit waiver requests to FDA.

From our databases, FDA estimates that of these 33,490 establishments, 29,370 have unique owner/operators. The remainder fall under owner/operators who register multiple establishments. The number of respondents for section 224 given in the burden table, 29,370 corresponds to the number of owner/operators annually registering one or more establishments. In addition, FDA estimates that 4,988 owner/operators, although they are required to register their establishments, are not required to list their devices because they are only initial importers and do not design, manufacture or otherwise process the devices. The number of respondents for section 223 given in the burden table, 24,382 corresponds to the number of owner/operators who annually list one or more devices (29,370 - 4,988 = 24,382).

In order to calculate the burden estimate for waiver requests for Section 224, we assume as stated above that less than one tenth of one percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 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 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than one percent (i.e., 1) of these will also request waivers each year.

We anticipate a small number of additional firms would enter the device industry over the next several years and would need to list and register. To the extent that a small fraction of these firms would request waivers, there may be small additional costs in the future.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the 2007 Amendments	FDA Form No.	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
222[2]	3673	2,600	1	2,704	0.5	1,352
223[2]	3673	24,382	1	24,382	0.25	6,095
224[2]		29,370	1	29,370	0.75	22,028
224[3]		2,600	1	2,600	0.5	1,300
224 (waiver request)[2]		20	1	20	1	20
224 (waiver request)[3]		1	1	1	1	1
					Total Hours	30,796

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

[2]One time burden.
[3]Annual increase in burden.

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 30,796 hours and a labor cost of $27 per hour including benefits, the cost for all affected establishments would be $ 831,492 ($27 per hour x 30,796 hours). In addition, we estimate that the Secretary will grant waivers to no more than 10% percent of requests made. FDA estimates that 3% (i.e., 1) of these establishments will not acquire access to the Internet and, therefore, need to request waivers annually. This annual rate was determined by the Agency's current estimates of staff expenses.

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

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

This is a new information collection.

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 - The Food and Drug Administration Amendments Act of 2007, sections 222, 223 and 224
Attachment 2 - Federal Register 60 day Notice