

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0436]

DDM  
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Certifier N. Hawkins

**Agency Information Collection Activities: Proposed Collection; Comment Request; Medical Device Registration and Listing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical device registration and listing.

**DATES:** Submit written and electronic comments on the collection of information by [*insert date 60 days after date of publication in the **Federal Register***].

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Medical Device Registration and Listing—21 CFR Parts 807.22, 807.31, and 807.40 (OMB Control No. 0910–0387—Extension)**

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires 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 FDA. This is accomplished by completing FDA Form 2891 “Registration of Device Establishment” and FDA Form 2892 “Medical Device Listing.” The term “device” is defined in section 201(h) of the act (21 U.S.C. 321) 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 on Form 2891 as part of its initial and updated registration information. In addition, each year, active, registered establishments must notify FDA of changes to the current registration and device listing for the establishment. Annual changes to current registration information are preprinted on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA’s Center for Devices and Radiological Health, even if no changes have occurred. Changes to listing information are submitted on Form 2892.

Under § 807.31 (21 CFR 807.31), each owner or operator is required 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. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made

anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements above, the owner or operator must be prepared to submit to FDA all labeling and advertising mentioned above (§ 807.31(e)).

Section 807.40 describes the role of the United States agent. The U.S. agent must reside or have a physical place of business in the United States, and each foreign establishment must submit U. S. agent information as part of its initial and updated registration process.

The information collected through these provisions is used by FDA to identify firms subject to FDA's regulations and is used to identify geographic distribution in order to effectively allocate FDA's field resources for these inspections and to identify the class of the device that determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can be easily identified.

The likely respondents to this information collection will be domestic and foreign device establishments and U.S. agents 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 estimates the burden of this collection of information as follows:

Estimated Annual Reporting Burden  
TABLE 1A.—ESTIMATED YEAR 1 ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a) and 807.40	2891 Establishment of Registration	2,900	1	2,900	.25	725
807.22(b)	2892 Medical Device Listing	4,400	1	4,400	.50	2,200

Estimated Annual Reporting Burden—Continued  
TABLE 1A.—ESTIMATED YEAR 1 ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a) and 807.40	2891a Annual Registration of Medical Device Establishment	25,100	1	25,100	.25	6,275
807.31(e)		200	1	200	.50	100
Total Year 1 Burden Hours						9,300

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 1B.—ESTIMATED SUBSEQUENT YEARS ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours Per Response	Total Hours
807.22(a) and 807.40	2891 Registration of Establishment	3,100	1	3,100	.25	775
807.22(b)	2892 Medical Device Listing	4,600	1	4,600	.50	2,300
807.22(a) and 807.40	2891a Annual Registration of Medical Device Establishment	25,100	1	25,100	.25	6,275
807.31(e)		200	1	200	.50	100
Total Year 2 and 3 Burden Hours						9,450

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

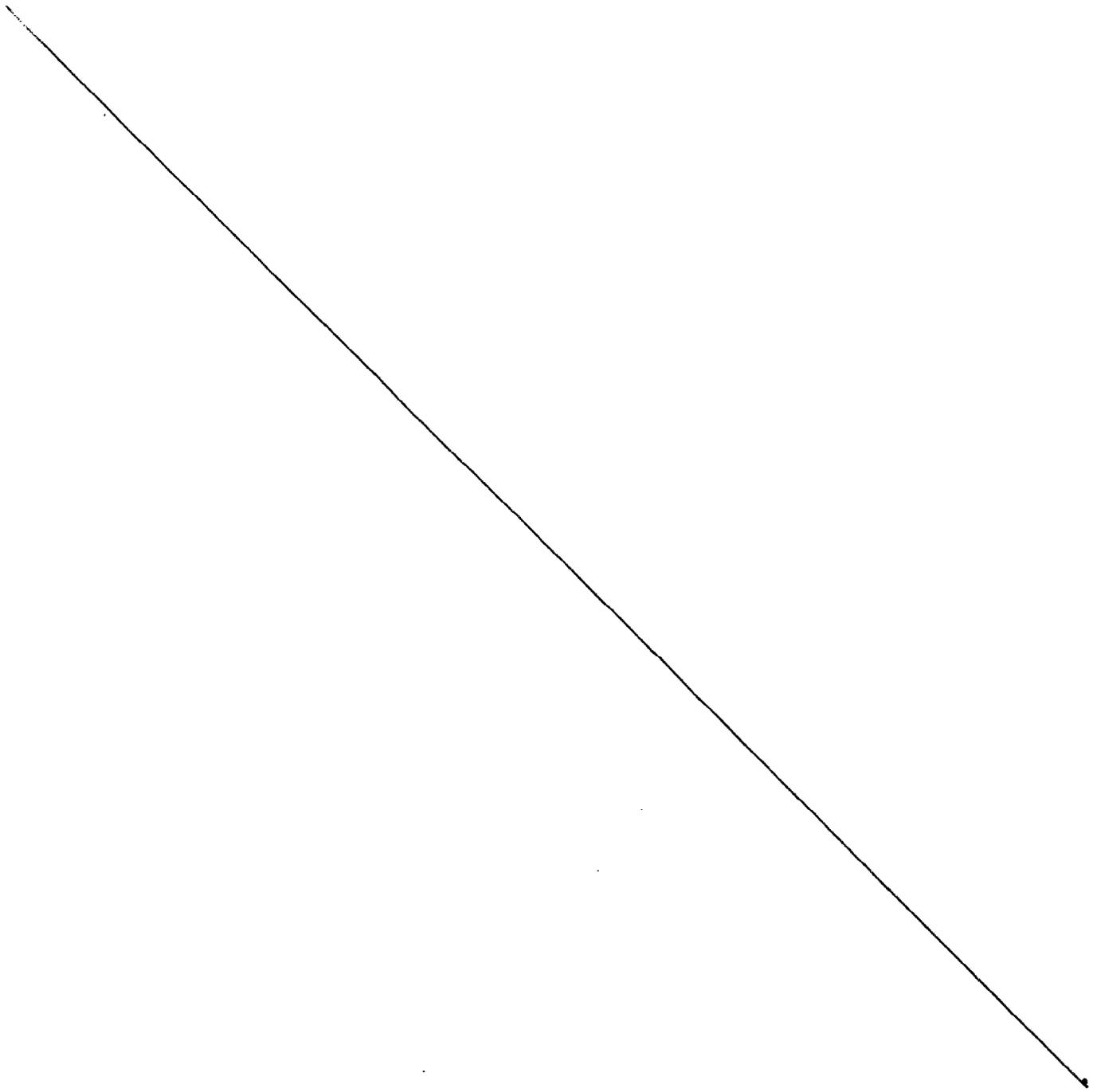
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours Per Recordkeeper	Total Hours
807.31	16,200	4	64,800	.50	32,400
Total Burden Hours					32,400

<sup>1</sup>The burdens are explained as follows:

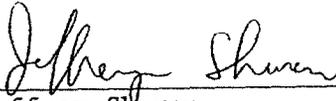
The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 9,450 hours, and recordkeeping burden hours for respondents is estimated to be 32,400 hours. The estimates cited in the tables above are based primarily upon the annual FDA accomplishment report, which includes actual FDA registration and listing figures from fiscal year (FY) 2003. These estimates are also based on FDA estimates of FY 2003 data from current systems, conversations with industry and trade association representatives, and from internal review of the documents referred to in the previous tables.

According to 21 CFR part 807, all owners/operators are required to list, and establishments and U.S. agents are required to register. Each owner/

operator has an average of two establishments, according to statistics gathered from FDA's registration and listing database. The database has 25,100 active establishments listed in it. Based on past experience, the agency anticipated that approximately 7,300 registrations will be processed during the first year, and 3,100 thereafter. FDA anticipates reviewing 200 historical files annually.



Dated: 10/22/04  
October 22, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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