Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25918 Filed 10–15–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0266]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 14, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with FDA. This is accomplished by completing FDA Form 2891 entitled ''Initial Registration of Device Establishment'' and FDA Form 2892 entitled ''Medical Device Listing.'' 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. On August 14, 2001, all hospitals who reprocess single-use devices will be required to register and list their activities. Under the Food and Drug Administration Modernization Act of 1997, foreign manufacturers are now required to register their establishments and list their devices, but foreign registration and listing will be covered under a separate information requirement. FDA will also accept voluntary registration and listings from firms not covered above that wish to be registered with FDA.

In addition, under § 807.31 (21 CFR 807.31), each owner or operator is required to maintain a 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)).

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 establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

In the **Federal Register** of July 6, 2001 (66 FR 35642), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED YEAR 1 ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,045	1	2,045	0.25	511
807.22(a) (hospital reuse manufacturers)	Form 2891 Initial Establishment Registration	2,000	1	2,000	0.25	500
807.22(b)	Form 2892 Device Listing—initial and updates	3,450	1	3,450	0.50	1,725
807.22(b) (hospital reuse manufacturers)	Form 2892 Device Listing—initial and updates	2,000	10	20,000	0.50	10,000
807.22(a)	Form 2891(a)—Registration Update	16,500	1	16,500	0.25	4,125
807.31(e)		200	1	200	0.50	100
Total year 1 burden hours						16,961

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

TABLE 2.—ESTIMATED SUBSEQUENT YEARS ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,245	1	2,245	0.25	561
807.22(b)	Form 2892 Device Listing—initial and updates	3,650	1	3,650	0.50	1,825
807.22(a)	Form 2891(a)—Registration Update	18,500	1	18,500	0.25	4,625
807.31(e)		200	1	200	0.50	100
Total year 2 and year 3 burden hours						7,111

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

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	9,900	10	99,000	0.50	49,500
Total burden hours					49,500

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

This year's submission has broken out annual costs into two distinct phases, and the tables above summarized the estimated annual reporting burden hours for medical device establishments to report in compliance with the provisions imposed by this regulation.

Hospital Reprocessing of Single-Use Medical Devices

On August 14, 2001, hospitals who reprocess single-use devices will be required to register their establishments and list those devices they reprocess. FDA has estimated that there will be approximately 2,000 such establishments that will fall into this category. The first year of the requirement will cause a one-time bolus of information to be submitted. FDA has separated the burden estimates into two tables to indicate year 1 (table 1 of this document) and subsequent year's estimates (table 2 of this document). Year 1 will include burden hours based on this bolus of submissions during the first year and subsequent year's estimates will indicate an adjustment for the new registrants for year 2 and beyond.

Burden Hour Explanation

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 16,961 hours, and recordkeeping burden hours for respondents is estimated to be 49,500 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) 2000. These estimates are also based on FDA estimates of FY 2000 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 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 16,500 active establishments listed in it. Based on past experience, the agency anticipates that approximately 4,045 registrations will be processed during the first year (because of hospitals who reprocess single-use), and 2,045 registrations thereafter. The agency also anticipates that approximately 5,450 initial and update device listings will be submitted the first year (due to hospitals who reprocess single-use devices), and 3,450 thereafter. FDA anticipates reviewing 200 historical files annually. Finally, because initial importers (currently estimated at 6,200) do not have to maintain historical files and because of the addition of 2,000 hospitals who reprocess single-use medical devices, FDA estimates that the number of recordkeepers required to maintain the initial historical information will be 9,900.

Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0267]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by November 15, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.