scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 9, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–27732 Filed 10–9–98; 3:44 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0494]

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 (the PRA).

DATES: Submit written comments on the collection of information by November 13, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 section 3507 of the PRA (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

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, ''Initial Registration of Device Establishment,'' and FDA Form 2892, ''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 pre-printed on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA's Center for Devices and Radiological Health (CDRH), even if no changes have occurred. Changes to listing information are submitted on Form 2892. Refurbishers/reconditioners are not required to register or list; however, FDA will accept voluntary registration and listings from firms 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, the owner or operator must be prepared to submit to FDA upon specific request all labeling and advertising mentioned in the previous paragraph (§ 807.31(e)).

The information collected through these provisions is used by FDA to identify firms subject to the agency's regulations and is used to identify geographic distribution in order to effectively allocate its field resources for these inspections and to identify the class of the device which determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can easily be 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 16, 1998 (63 FR 38409), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED 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	1,462	1	1,462	.25	366
807.22(b)	Form 2892—Device Listing (initial and update)	5,640	1	5,640	.50	2,820
807.22(a)	Form 2891(a)—Registration Update	22,000	1	22,000	.25	5,500
807.31(e)		200	1	200	.50	100
Total						8,786

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	7,900	10	79,000	0.5	39,500

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

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 8,786 hours, and recordkeeping burden hours for respondents is estimated to be 39,500 hours. The estimates cited in Tables 1 and 2 of this document are based primarily upon the annual FDA Accomplishment Report, which includes actual FDA registration and listing figures from fiscal year (FY) 1997. These estimates are also based on conversations with industry and trade association representatives, and internal review of the FDA forms and 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 Data Base. The data base has 22,000 establishments listed in it. Based on past experience, the agency anticipates that approximately 1,462 registrations will be processed annually, and that 5,640 initial and update device listings will be submitted. Although FDA only processed 12,237 annual registrations during FY 1997 due to a delay in sending out the annual registration forms, the normal amount of processing of annual registrations in the past has been 22,000. FDA anticipates reviewing 200 historical files annually. Finally, because initial importers (currently estimated at 6,200) do not have to maintain historical files, FDA estimates that the number of recordkeepers required to maintain the initial historical information will be 7,900 (which is the number of establishments, 22,000 minus the number of initial importers, 6,200, divided by 2, the average number of establishments per owner/operator).

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27493 Filed 10–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0147]

Agency Information Collection Activities; Announcement of OMB Approval; Access to Mammography Services Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Access to Mammography Services Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 23, 1998 (63 FR 39581), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0383. The approval expires on September 30, 2001.

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27492 Filed 10–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: September 1998

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of September 1998, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ADDIS, HOWARD ..... SEATTLE, WA	10/20/1998
ARTMAN, CARL JR ..... HAZELWOOD, MO	10/20/1998
ASHBAUGH, KAREN LOUISE SAN ANTONIO, TX	10/20/1998
BAUGHER, DENNIS L ..... FT MYERS, FL	10/20/1998
CACERES, MARIO ..... BLUE BELL, PA	10/20/1998
CRITTENDEN, JAMES C ..... MEMPHIS, TN	10/20/1998
DIANA, KATHLEEN ANN ..... FORT WORTH, TX	10/20/1998
DOUBLEDAY, LINDA ..... POPE, MS	10/20/1998
ELROSE HEALTH SERVICES, INC ..... DETROIT, MI	10/20/1998
EZEUDE, CHRISTOPHER UJU	10/20/1998