

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

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

<sup>1</sup> 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.*

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**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.*

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**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
<b>PROGRAM-RELATED CONVICTIONS</b>	
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