TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.11(c)	10,000	0.0050	50	20	1,000		$1,000
900.12(c)(2)	9,800	4,080	39,984,000	5 Minutes	3,332,000		
900.12(j)(1)	10	1	10	1	10		
900.12(j)(2)	1	1	1	50	50		
900.15(d)(3)(ii)	10,000	0.0020	20	2	40		$100
900.18(c)	10,000	0.0005	6	2	12		$60
900.18(e)	10	0.1000	1	1	1		$10
TOTAL					3,434,010	$50	$1,170

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	Total Operating & Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)	10,000	1	10,000	1	10,000	
900.11(b)(1)	1,000	1	1,000	1	1,000	
900.12(c)(4)	10,000	1	10,000	1	10,000	
900.12(e)(13)	6,000	52	312,000	0.125	39,000	
900.12(f)	10,000	1	10,000	1	10,000	
900.12(h)	10,000	2	20,000	0.5	10,000	$20,000
TOTAL					82,000	$20,000

[1] There are no capital costs associated with this collection of information.

All costs of implementing requirements for certification of mammography facilities will be borne by accreditation bodies; the incremental costs that accreditation bodies will face are not expected to be significant. The collection's burden is based upon the estimated number of summaries received by FDA, which in turn is based on the estimated number of examinations expected to be performed in a given year. If mammography examinations increase in number in subsequent years, which is expected for at least the foreseeable future, the annual burden and costs to meet this requirement will increase.

Included in the burden estimate is the FDA estimate for mammography lay summaries, which is the practice of notifying the patient in layman's terms of the results of the patient's mammography examination. FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that those facilities perform a total of 40 million mammography examinations in a year. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 percent of the cases in which there is a finding of ''Suspicious'' or ''Highly suggestive of malignancy,'' the facility is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5 minute call from the health professional to the patient.

Dated: July 10, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0356]

Agency Information Collection Activities; Announcement of OMB Approval; Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of May 23, 2000 (65 FR 33329), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 0910–0443. The approval expires on June 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: July 10, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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