Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 30, 2003.

Julie Brown,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–28090 Filed 11–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–576, CMS–3427, CMS–R–282, CMS–372S]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Organ Procurement Organization (OPO) Request for Designation and Supporting Regulations in 42 CFR 486.304, 486.306, and 486.307; *Form No.:* CMS–576 (OMB# 0938–0512); *Use:* The information provided on this form serves as a basis for certifying OPOs for participation in the Medicare and Medicaid programs and will indicate whether the OPO is meeting the specified performance standards for reimbursement of service; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 59; *Total Annual Responses:* 59; *Total Annual Hours:* 118.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report and Supporting Regulations in 42 CFR 488.60; *Form No.:* CMS–3427 (OMB# 0938–0360); *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage; *Frequency:* Every three years; *Affected Public:* Business or other for-profit institutions, Not-for-profit institutions; *Number of Respondents:* 4000; *Total Annual Responses:* 1,320; *Total Annual Hours:* 440.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare + Choice (M+C) Organization Appeals and Grievance Data Disclosure Requirements and Supporting Regulations in 42 CFR 422.64, 422.111, and 422.560–422.626; *Form No.:* CMS–R–282 (OMB# 0938–0778); Use: M+C organizations will collect information on appeals and grievance dispositions to help CMS monitor plan performance and to provide information to beneficiaries to help them make informed decisions about their or potential health plans' performance; *Frequency:* Semi-Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 211 T*Total Annual Responses:* 422 *Total Annual Hours:* 422.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.180 and 441.300-.310; *Form No.:* CMS–372(S) (OMB# 0938–0272); *Use:* States request waivers in order for beneficiaries to have the option of receiving hospital services in their homes. States with an approved waiver under section 1915(c) of the Act are required to submit the CMS–372(S) annually in order for CMS to: (1) Verify that State assurances regarding waiver cost-neutrality are met, and (2) determine the waiver's impact on the type, amount and cost of services provided under the State plan and health and welfare of recipients; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 50; T*Total Annual Responses:* 277; *Total Annual Hours:* 20,775.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 30, 2003.

Julie Brown,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–28091 Filed 11–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0482]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Facilities, Standards, and Lay Summaries for Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 mammography facilities, standards, and lay summaries for patients under part 900 (21 CFR part 900).

DATES: Submit written or electronic comments on the collection of information by January 6, 2004.

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 Division of Dockets Management (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 listed below.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Mammography Facilities, Standards, and Lay Summaries for Patients—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

Public Law 102–539, the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 (Public Law 105–248) establishes the authority for a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for 4 years from its original expiration date of 1998 until 2002, and also modified some of the provisions. The most significant modification from a report and recordkeeping viewpoint under § 900.12(c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient.

FDA, under this regulation, collects information from accreditation bodies and mammography facilities by requiring each accreditation body to submit an application for approval and to establish a quality assurance program. On the basis of accreditation, facilities are certified by FDA and must prominently display their certificate. FDA uses the information to ensure that private, nonprofit organizations or State agencies meet the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services. Information collected from mammography facilities has also been used to ensure that the personnel, equipment, and quality systems has and continues to meet the regulations under MQSA and will be used by patients to manage their health care properly. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

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

TABLE 1.—ESTIMATED ANNUAL RECORDING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
900.3	1	0.33	0.33	60	20		
900.3(b)(3)	1	0.33	0.33	60	20	$50	
900.3(c)	5	0.33	1.67	15	25		
900.3(e)	1	0.1	0.1	1	0.1		
900.3(f)(2)	1	0.1	0.1	200	20		
900.4(c) and (d)	9,200	0.33	3,067	1	3,067		
900.4(e)	9,450	1	9,450	8	75,600		
900.4(f)	276	1	276	7	1,932		
900.4(h)	5	1	6,130	1	6,130		
900.4(i)(2)	1	0.33	0.33	1	0.33		

TABLE 1.—ESTIMATED ANNUAL RECORDING BURDEN[1]—Continued

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
900.6(c)(1)	1	0.1	0.1	1	0.1		
900.11(b)(1)	9,200	0.33	3,067	2	6,134		
900.11(b)(2)	250	1	250	2	500		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	9,200	0.04	368	5	1,840		$1,000
900.12(c)(2)	9,200	3,478	36,000,000	5 Minutes	3,000,000		
900.12(j)(1)	25	1	25	1	25		
900.12(j)(2)	25	0.08	2	50	100		
900.15(c)	9,200	0.05	46	2	92		
900.15(d)(3)(ii)	9,200	0.0001	0.92	2	1.8		$10
900.18(c)	9,300	0.00032	3	2	6		$30
900.18(e)	10	0.0100	0.1	1	0.1		$10
FDA Form 3422	800	1	800	.25	200		
TOTAL					3,095,716	$50	$1,040

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
900.3(f)(1)	5	0.02	0.1	200	20	
900.4(g)	1	0.33	0.33	1	0.33	
900.12(c)(4)	9,200	1	9,200	1	9,200	$18,400
900.12(e)(13)	9,200	52	478,400	0.125	59,800	
900.12(f)	9,200	1	9,200	5	46,000	
900.12(h)	9,200	2	18,400	0.5	9,200	
TOTAL					124,220	$18,400

The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

The total capital cost associated with these regulations is $50 (§ 900.3(b)(3)). This is a one-time start up cost associated with the application for approval as an accreditation body.

The total operating and maintenance cost associated with these requirements is: $19,440. This is the cost that facilities bear to maintain records under the initial and final mammography regulations.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28006 Filed 11–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1168]

Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Quantitative Risk Assessment and Risk Management Action Plan; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.