serve as the basis for MHS performance guarantees. To meet these requirements, CMS has developed a performance monitoring system for MHS. This system includes measures of clinical performance that require the collection of clinical data from the medical records of a sample of Medicare beneficiaries. Medical record abstraction will be performed in two phases: The first, a pilot test, will take place after approximately six months of program operations, and the second, the full study. CMS will obtain active informed consent from the affected beneficiaries prior to reviewing medical records; *Frequency:* Reporting—Other: Only Once; *Affected Public:* Individuals or Households and Business or other for-profit; *Number of Respondents:* 26,643; *Total Annual Responses:* 26,643; *Total Annual Hours:* 12,416.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare—Determining Third Party Liability (TPL) State Plan Preprint and Supporting Regulations in 42 CFR 433.138; *Form Number:* CMS–R–0107 (OMB#: 0938–0502); *Use:* Medicaid beneficiaries frequently have third party resources which are legally obligated to pay medical claims before Medicaid pays. Section 42 CFR 433.138 requires State Medicaid agencies to take specific steps to identify third party resources and determine their legal liability to pay for services under the plan. The collection of TPL information results in significant program savings to the extent that liable third parties can be identified and payments can be made for services that would otherwise be paid for by the Medicaid program. The State Medicaid agencies are the primary users of the collected data. Whenever States identify third party resources, pertinent information is entered into the State's Medicaid Management Information System (MMIS). This enables the State to advise the provider to bill the third party and to seek reimbursement in situations where Medicaid TPL claims have been paid; *Frequency:* Recordkeeping—On occasion; *Affected Public:* Individuals or Households and Federal, State, Local and Tribal Government; *Number of Respondents:* 2,700,000; *Total Annual Responses:* 2,700,000; *Total Annual Hours:* 472,259.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Retirement Benefit Information (BBA '97); *Form Number:* CMS–R–285 (OMB#: 0938–0769); *Use:* The Request for Retirement Benefit Information form is used to obtain retirement benefit information from beneficiaries that purchase Medicare Part A coverage. The Social Security Administration (SSA) will use this information to determine if a beneficiary meets the requirements to qualify for a Medicare Part A premium reduction; *Frequency:* Reporting—On occasion; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 1500; *Total Annual Responses:* 1500; *Total Annual Hours:* 375.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on January 30, 2006.

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 21, 2005.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–24567 Filed 12–29–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0216]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Humanitarian Use Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 24, 2005 (70 FR 61455), 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 0910–0332. The approval expires on December 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–8110 Filed 12–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0195]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #9

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by January 30, 2006.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie

Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #9

The Mammography Quality Standards Act (MQSA) Final Regulations: Modifications and Additions to Policy Guidance Help System 9 provides guidance to mammography facilities and their personnel on a variety of issues involving the quality standards for mammography (§ 900.12 (21 CFR 900.12)). Use of the guidance results in new collections of information. Facilities are required to provide patients with lay summaries of the results of their mammography examinations (§ 900.12(c)(2)). This guidance document provides information on how to address a patient's refusal to receive a lay summary and recommends that the facility document why it was unable to meet this requirement. Additionally, the guidance addresses interpreting physician initial requirements (§ 900.12(a)(1)(i)(B)(*2*)), including recommendations on how to document the alternative to Board Certification for foreign-trained physicians.

The likely respondents are mammography facilities and their personnel who are subject to the MQSA quality standards requirements.

In the **Federal Register** of July 15, 2005 (70 FR 41043), FDA published a 60-day notice requesting comments on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Reporting of refusal of lay summary	915	1	915	0.5	458

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	Number of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours Per Record	Total hours
Documentation of foreign-trained physicians' qualifications	92	1	92	8	736

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

There are a total of 9,150 MQSA-certified facilities. Using past experience, FDA estimates that 10 percent of these facilities will receive patient requests that lay summary results not be sent. We also estimate that the facility will spend 0.5 hours per patient obtaining the patient's written request, filing that form in the patient's record and forwarding the summary to the patient's designee. With respect to foreign-trained physicians, past experience indicates that this situation arises very infrequently. We estimate that only 1 percent of MQSA-certified facilities will have to maintain records documenting the qualifications of foreign-trained physicians.

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–8111 Filed 12–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0217]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Cosmetic Product Voluntary Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Cosmetic Product Voluntary Reporting Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2005 (70 FR 59073), 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 0910–0030. The approval expires on December 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–8112 Filed 12–29–05; 8:45 am]

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