Annual Responses: 125,000; *Total Annual Hours:* 62,500.

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/regulations/pra/*, 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 on (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 November 7, 2005.

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

Dated: September 29, 2005.

Michelle Shortt,

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

[FR Doc. 05–20101 Filed 10–6–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1557 and CMS–1880/1882 and CMS 10142]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & 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 & Medicaid Services (CMS) 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:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and supporting regulations under 42 CFR 493.1–493.2001; *Form Number:* CMS–1557 (OMB#: 0938–0544); *Use:* This form is used by the State agency to determine a laboratory's compliance with CLIA. This information is needed for a laboratory's CLIA certification and recertification; *Frequency:* Recordkeeping and Reporting—Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 25,000; *Total Annual Responses:* 12,500; *Total Annual Hours:* 6,250.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Request for Certification as a Supplier of Portable X-Ray Services and Portable X-Ray Survey Report Form under the Medicare and Medicaid Program—Portable X-Ray Survey Report and Supporting Regulations under 42 CFR 486.100–486.110; *Form Number:* CMS–1880/1882 (OMB#: 0938–0027); *Use:* The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The CMS–1882 is the survey form that records survey results. The CMS–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. This information serves as a screen for the State survey agency to determine if the portable X-ray supplier has the basic capabilities to participate in the Medicare program. CMS will use this information to make certification decisions; *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 655; *Total Annual Responses:* 98; *Total Annual Hours:* 172.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage and Prescription Drug Plans (PDP) contained in 42 Code of Federal Regulation (CFR): 422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.251, 423.258, 423.265, 423.272, 423.279, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350 ; *Form Number:* CMS–10142 (OMB#: 0938–0944); *Use:* Under the Medicare Modernization Act, Medicare Advantage Organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing bid to CMS for approval. The BPT software is used by MAOs and PDPs to price their plan benefit package. The BPT software is used by CMS to review and approve the plan pricing proposed by each organization; *Frequency:* Reporting '' On occasion, Annually and As required by new legislation; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 350; *Total Annual Responses:* 350; *Total Annual Hours:* 12,050.

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://www.cms.hhs.gov/regulations/pra/,* 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 on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on December 6, 2005.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 30, 2005.

Michelle Shortt,

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

[FR Doc. 05–20228 Filed 10–6–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10171]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed which may result in public harm.

Section 1860D–23 and 1860D–24 of the Social Security Act, added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), requires the Secretary to establish requirements for prescription drug plans to ensure the effective coordination between Part D plans, State pharmaceutical assistance programs and other payers. These requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464.

Part D sponsors will be responsible for making system changes related to enrollment file sharing, claims processing and payment, reconciliation and tracking of the true out-of-pocket expenditures of beneficiaries prior to the implementation of Part D (January 1, 2006). System changes must also be implemented by State pharmaceutical assistance programs so that they may provide additional drug benefits at the pharmacy to Part D beneficiaries. In addition to making system changes, these changes must be tested, which will require additional time prior to January 1, 2006. Failure to make system changes may result in the delay in the implementation of the program and may result in a direct harm to beneficiaries since delays or mistakes in claims processing may result in beneficiaries not receiving their medications, or being unable to pay for medications out-of-pocket until the system issue is resolved.

CMS is requesting OMB review and approval of this collection by November 8, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by November 7, 2005.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Coordination of Benefits between Part D Plans and Other Prescription Coverage Providers; *Use:* This information is necessary to assist with coordination of prescription drug benefits provided to the Medicare beneficiary at the pharmacy; *Form Number:* CMS–10171 (OMB#: 0938–NEW); *Frequency:* On occasion and monthly; *Affected Public:* Business or other for-profit, Federal, State, Local and Tribal Government; *Number of Respondents:* 56,320; *Total Annual Responses:* 2,153,767,270; *Total Annual Hours:* 1,017,914.

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://www.cms.hhs.gov/regulations/pra* 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received by the designees referenced below by November 7, 2005: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Melissa Musotto, CMS–10171. and, OMB Human Resources and Housing Branch, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 30, 2005.

Michelle Shortt,

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

[FR Doc. 05–20229 Filed 10–6–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0178]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Regulations Under the Federal Import Milk Act

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 November 7, 2005.

ADDRESSES: 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: Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Under the regulations implementing the Federal Import Milk Act (FIMA) (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the