

*Annual Responses:* 1,100; *Total Annual Hours:* 275.

(3) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1—493.2001; *Form No.:* HCFA-0209 (OMB# 0938-0151); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. Information on personnel qualifications of all technical personnel is needed to ensure the sample is representative of all laboratories; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal government, and State, local or tribal government; *Number of Respondents:* 22,500; *Total Annual Responses:* 11,250; *Total Annual Hours:* 5,625.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's 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](mailto: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 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 21, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02-30366 Filed 11-29-02; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare and Medicaid Services**

[Document Identifier: CMS-855]

**Agency Information Collection Activities: Proposed collection; 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), 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.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Federal Health Care Programs Provider/Supplier Enrollment Application; *Form No.:* CMS-855 (OMB# 0938-0685); *Use:* This information is needed to enroll providers and suppliers into the Medicare program by identifying them, pricing and paying their claims, and verifying their qualifications and eligibility to participate in Medicare; *Frequency:* Initial enrollment/recertification and Every three years; *Affected Public:* Business or other for-profit, individuals or households, and not-for-profit institutions; *Number of Respondents:* 274,000; *Total Annual Responses:* 274,000; *Total Annual Hours:* 642,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's 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](mailto: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 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 25, 2002.

**Julie E. Brown,**

*Acting Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02-30377 Filed 11-26-02; 11:20 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare and Medicaid Services**

[Document Identifier: CMS-R-250]

**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.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* SNF Resident Assessment MDS Data and Supporting

Regulations in 42 CFR, Sections 413.337, 413.343, 424.32, and 483.20; *Form No.*: CMS-R-250 (OMB# 0938-0739); *Use*: Skilled Nursing Facilities (SNFs) are required to submit the resident assessment data as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337. Pursuant to sections 4204(b) and 4214(d) of OBRA 1987, the current requirements related to the submission and retention of resident assessment data for the 5th, 30th, 60th, and 90th days following admission, necessary to administer the payment rate methodology described in Section 413.337, are subject to the Paperwork Reduction Act. The burden associated with this is the SNF staff time required to complete the Minimum Data Set (MDS), SNF staff time to encode, and SNF staff time spent in transmitting the data.; *Frequency*: Monthly; *Affected Public*: Business or other for-profit, and Not-for-profit institutions; *Number of Respondents*: 17,000; *Total Annual Responses*: 2,657,859; *Total Annual Hours*: 1,993,394.

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/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto: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: November 21, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02N-0486]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing Act of 1987**

**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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100-293).

**DATES**: Submit written or electronic comments on the collection of information by January 31, 2003.

**ADDRESSES**: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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**: Karen Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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 set forth in this document.

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

**Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR part 3 (OMB Control Number 0910-0435)—Extension**

FDA is requesting OMB approval under the PRA for the reporting and recordkeeping requirements contained in the regulations implementing PDMA. PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk of counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as American goods returned causing a health and safety risk to American consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against American manufacturers and had