Medicaid Services (CMS), through its Office of Research, Development and Information (ORDI), is conducting the Medical Adult Day-Care Services Demonstration. Five Medicare certified home health agencies were selected by CMS through a competitive process to participate in the demonstration. These five demonstration sites are Aurora Visiting Nurse Association (Milwaukee, Wisconsin), Doctor's Care Home Health (McAllen, Texas), Landmark Home Health Care Services (Allison Park, Pennsylvania), Metropolitan Jewish Health System (Brooklyn, New York) and Neighborly Care Network (St. Petersburg, Florida). *Form Number:* CMS–10204 (OMB#: 0938–NEW); *Frequency:* Reporting—One-time; *Affected Public:* Individuals and Households, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 55; *Total Annual Responses:* 110; *Total Annual Hours:* 297.5.

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/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 on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: January 26, 2007.

Michelle Shortt,

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

[FR Doc. E7–1685 Filed 2–1–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10079 and CMS–R–245]

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:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR 412.64; *Use:* Section 304(c) of Public Law 106–554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The 2007/2008 revised survey will provide for the collection of hospital-specific wages and hours data for a 1-year prospective reporting period (July 1, 2007 through June 30, 2008), additional clarifications to the survey instructions, the elimination of the RN subcategories, some refinements to the definitions for the occupational categories, and the inclusion of additional cost centers that typically provide nursing services. The 2007/2008 Medicare occupational mix survey will be applied beginning with the FY 2010 wage index. Each of the approximately 3,600 inpatient prospective payment system providers participating in the Medicare program will be required to complete the revised Medicare Wage Index Occupational Mix Survey. The revised survey will be forwarded to hospitals through CMS's fiscal intermediaries and will be made available on CMS's Web site. *Form Number:* CMS–10079 (OMB#: 0938–0907); *Frequency:* Reporting: Yearly, Biennially and Occasionally; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 3,600; *Total Annual Responses:* 3,600; *Total Annual Hours:* 1,728,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs OASIS Collection Requirements as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.55, 484.205, 484.245, 484.250; *Use:* The Outcome and Assessment Information Set (OASIS) is a requirement for one of the Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet in order to participate in the Medicare program. Specifically, the CoP at § 484.55 requires that each patient receive from an HHA a patient-specific, comprehensive assessment that identifies a patient's continuing need for home care and meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, to evaluate non-maternity patients. The data collected using OASIS is used for three main purposes: Assessing and improving the quality of care provided by an HHA, submitting and paying claims for Medicare home health services, and surveying the HHAs in accordance with Section 1891 of the Social Security Act (the Act). *Frequency:* Recordkeeping and Reporting—upon patient assessment; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 8,277; *Total Annual Responses:* 10,105,827; *Total Annual Hours:* 11,977,601.

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/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 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 April 3, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 26, 2007.

Michelle Shortt,

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

[FR Doc. E7–1686 Filed 2–1–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0036]

Agency Emergency Processing Under Office of Management and Budget Review; Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Labeling Comprehension Study

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns an experimental study to test labeling statement alternatives for certain prescription and over-the-counter (OTC) drug product labeling.

DATES: Fax written comments on the collection of information by March 5, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320) and is essential to the agency's mission to protect the public health and safety. Section 17 of the Best Pharmaceuticals for Children Act (the BPCA) (Public Law 107–109) requires FDA to issue a final rule mandating the addition of a statement to the labeling of each drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355). Under the BPCA, the labeling statement is required to include: (1) A toll-free number for consumers to use to report drug product side effects and (2) a statement that the number is to be used only for reporting side effects and is not intended to seek or obtain medical advice (the side effects statement). The use of normal clearance procedures would further delay FDA's issuance of a final rule to comply with this congressional mandate.

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.

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Labeling Comprehension Study

On April 22, 2004 (69 FR 21778), FDA published a proposed rule with a proposed side effects statement for certain prescription drug product labeling and a proposed side effects statement for certain OTC drug product labeling. In the proposed rule, FDA solicited comments on the wording of these side effects statements. We received 12 comments suggesting changes to the specific wording of the proposed side effects statements. We also received several comments suggesting that FDA engage in research to study consumer comprehension of the wording of the proposed side effects statements. Among the reasons cited for testing the statements were: (1) To determine the best and most precise wording for the statements, (2) to evaluate consumer comprehension of the proposed statements, and (3) to address concerns that consumers who read the statement will mistakenly call FDA in search of medical advice. In addition, during the clearance process for the proposed rule, both the Office of Information and Regulatory Affairs of OMB and the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services suggested that FDA conduct consumer studies on the wording of the side effects statements. After the publication of the proposed rule and based on the comments received, FDA decided to conduct research to study the wording of the proposed side effects statements before issuing a final rule.

FDA conducted two focus groups (OMB Control No. 0910–0497) to narrow the field of potential statement alternatives. Based on the findings from the focus groups, FDA has selected several statements for quantitative testing in an experimental study of consumer comprehension. The experimental study will test several ways of stating the required information for maximum comprehension of factual information and necessary action. The experimental study will provide quantitative data to inform FDA's selection of the side effects statements to fulfill the requirements of the BPCA. Each participant will be exposed to only one side effects statement, in a ''between-subjects'' or ''monadic'' design. Participants initially will see one statement in the context of either a prescription drug bottle or an OTC Drug Facts label, depending on which condition they are in, and will all answer the same series of questions. For the remainder of the study, each participant will see the statement as they answer questions specifically about the statement. The experimental study data will be collected via the Internet from members of a consumer panel maintained by an external research organization. Panel members are recruited by a variety of means designed to reflect all segments of the population. They are required to have a computer with Internet access. Studies begin with an e-mailed invitation to the sampled