transitional pass-through payment provisions as required by section 1833(t)(6) of the Social Security Act. *Form Number:* CMS–10052 (OMB#: 0938–0857); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 12; Total *Annual Responses:* 12; Total *Annual Hours:* 192.

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center (ASC) Health Insurance Benefit Agreement, ASC Request for Certification, ASC Survey Report and Supporting Regulations in 42 CFR 416.41, 416.43, 416.47, and 416.48; *Use:* The ASC Health Insurance Benefits Agreement form is utilized for the purpose of establishing eligibility for payment under Title XVIII of the Social Security Act. The ASC Request for Certification form is utilized as an application for facilities wishing to participate in the Medicare program as an ASC. This form initiates the process of obtaining a decision as to whether the conditions of coverage are met. It also promotes data retrieval from the Online Data Input Edit (ODIE system, a subsystem of the Online Survey Certification and Report (OSCAR) system by the Centers for Medicare and Medicaid Services (CMS) Regional Offices (RO)). The ASC Report Form is an instrument used by the State survey agency to record data collection in order to determine supplier compliance with individual conditions of coverage and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ODIE/OSCAR system at the CMS ROs. This form includes basic information on compliance (*i.e.*, met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself; *Form Number:* CMS–370, 377, 378, R–54 (OMB#: 0938–0266); *Frequency:* Annually and Other: once; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 4,312; Total *Annual Responses:* 4,312; Total *Annual Hours:* 2,241.

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@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: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 10, 2004.

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.

[FR Doc. 04–25720 Filed 11–18–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10102]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

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:* New Collection; *Title of Information Collection:* National Implementation of the Hospital CAHPS Survey; *Form No.:* CMS–10102 (OMB# 0938–NEW); *Use:* Hospital CAHPS, part of the Hospital Quality Alliance, is an effort to provide comparative performance information on hospitals to the public. HCAHPS includes a standardized survey instrument and data collection protocol allowing for flexibility in the mode of administration. The goals of the HCAHPS are to offer consumers choice and create incentives for hospitals to improve performance in areas that are important to patients. The current version of the questionnaire and implementation strategy has been tested and modified to reflect public input. CMS will begin training and implementation for HCAHPS following National Quality Forum endorsement and the Office of Management and Budget approval.; *Frequency:* Monthly; *Affected Public:* Individuals or households; *Number of Respondents:* 2,855,250; *Total Annual Responses:* 2,855,250; *Total Annual Hours:* 285,525.

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.

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: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 10, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–25721 Filed 11–18–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992; Extension of Application Deadline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of extension of application deadline.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension for acceptance of applications to its continuous marketing applications (CMA) Pilot 2 program implemented under the guidance for industry entitled ''Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' The extension applies only to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) review divisions that have not received acceptable applications for participation in the Pilot 2 program.

DATES: Submit written or electronic comments on agency guidances at any time. FDA will accept applications through December 31, 2004, for participation in the CMA Pilot 2 program per the restrictions described in the **SUMMARY** section of this document.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–3937, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 6, 2003 (68 FR 57696), FDA announced the availability of a guidance entitled ''Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' This guidance is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). The guidance discusses how the agency will implement a CMA Pilot 2 program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of development for certain Fast Track drug and biological products.

Under the CMA Pilot 2 program, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to be considered for participation in the CMA Pilot 2 program. The CMA Pilot 2 program is an exploratory program, and FDA will evaluate its impact on the investigational phase of drug development. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. The guidance provides information regarding the selection of applications for the CMA Pilot 2 program, the formation of agreements between FDA and applicants on the investigational new drug (IND) communication process, and other procedural aspects of the CMA Pilot 2 program.

Per section III.A.4 of the guidance, applicants were originally asked to apply for participation in the CMA Pilot 2 program from October 6, 2003, through December 8, 2003. For review divisions that had not received any acceptable CMA Pilot 2 program applications by December 8, 2003, applications were also accepted between February 9, 2004, and September 30, 2004. This notice further extends that deadline to December 31, 2004, to ensure inclusive and relevant results from the CMA Pilot 2 program. A description of the application submission process, evaluation criteria, and selection process is in the guidance. Applications will be accepted only in CDER and CBER divisions that have not previously selected a Pilot 2 application. Information regarding the CDER and CBER divisions that are available to select the CMA Pilot 2 program application can be found on FDA's Web site at *http://www.fda.gov/cder/pdufa/CMA.htm*. For each of these divisions, the first application received that adequately meets the evaluation criteria will be accepted into the CMA Pilot 2 program and applicants will be informed within 6 weeks of application submission.

II. Electronic Access

Persons with access to the Internet can obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm* or at *http://www.fda.gov/cber/guidelines.htm*.

Dated: November 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25799 Filed 11–17–04; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0460]

Draft Guidance for Industry on Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of November 4, 2004. This document announced the availability of a draft guidance for industry entitled ''Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers.'' The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–24675, appearing on page 64314 in the **Federal Register** of Thursday, November 4, 2004, the following correction is made:

1. On page 64314, in the second column, ''Docket No. 2004N–0087'' is corrected to read ''Docket No. 2004D–0460''.