

Information Collection: Application for Participation in the Medicare Care Management Performance Demonstration; *Form Number:* CMS–10165 (OMB#: 0938–0965); *Use:* The Medicare Care Management Performance (MCMP) Demonstration and its corresponding Report to Congress are mandated by the section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 649 of the MMA provides for the implementation of a “pay for performance” demonstration under which Medicare would pay incentive payments to physicians who (1) adopt and use health information technology; and (2) meet established standards on clinical performance measures. This demonstration will be held in four states, Arkansas, California, Massachusetts, and Utah. Providers that are enrolled in the Doctors’ Office Quality—Information Technology (DOQ–IT) project are eligible to participate in the demonstration. To enroll in the MCMP Demonstration, a physician/provider must submit an application form. The information collected will be used to assess eligibility for the demonstration; *Frequency:* Reporting—One-time only; *Affected Public:* Business or other for-profit; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 133.

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/prd/>, 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 13, 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: October 6, 2005.

Michelle Shortt,

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

[FR Doc. 05–20517 Filed 10–13–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10064]

Agency Information Collection Activities: Submission for OMB Review; 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), 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 function; (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:* Minimum Data Set (MDS) for Swing Bed Hospitals and Supporting Regulations in 42 CFR 483.20 and 413.337; *Form No.:* CMS–10064 (OMB # 0938–0872); *Use:* As required under Section 1888(e)(7) of the Social Security Act, swing bed hospitals must be reimbursed under the skilled nursing facility prospective payment system. CMS uses the MDS data to reimburse swing bed hospitals for SNF-level care furnished to Medicare beneficiaries. The MDS3.0 is currently being developed with plans for field testing to begin in 2006 with the expectation of completion in 2007. At that time, CMS will analyze the data derived from the study, including the implementation of the new version of the MDS for swing bed hospitals. Since we do not have the MDS3.0 version available, we are requesting an extension for the current SB–MDS.; *Frequency:* Reporting—Other (days 5, 14, 30, 60, and 90 of stay); *Affected Public:* Not-for-profit institutions, and State, Local, and Tribal governments; *Number of Respondents:* 820; *Total*

Annual Responses: 92,789; *Total Annual Hours:* 51,314.

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/prd/>, 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 14, 2005. OMB Human Resources and Housing Branch, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 6, 2005.

Martique S. Jones,

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

[FR Doc. 05–20521 Filed 10–13–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on November 3, 2005, from 8 a.m. to 5:30 p.m., and on November 4, 2005, from 8 a.m. to 3:30 p.m.

Location: Holiday Inn Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD 20879.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–

741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2005, in the morning, the committee will hear updates on the following topics: (1) West Nile Virus; (2) draft guidance on nucleic acid testing (NAT) for human immunodeficiency virus (HIV)-1 and hepatitis C virus (HCV); Testing, product disposition, and donor deferral and re-entry; (3) summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability held on September 19 and 20, 2005; and (4) re-entry of donors deferred based on hepatitis B core antigen (anti-HBc) test results. The committee will discuss approaches to over-the-counter (OTC) home-use HIV test kits the rest of the day. On November 4, 2005, in the morning, the committee will hear information on serious adverse events resulting from interference with measurement of blood glucose following infusion of maltose-containing immune globulin intravenous (human) and will discuss Alpha-1-Proteinase Inhibitor products. In the afternoon, the committee will hear an overview of the research programs of the Office of Blood Research and Review, Center for Biologics Evaluation and Research, as presented to a subcommittee of the Blood Products Advisory Committee during their site visit on July 22, 2005, and discuss a subcommittee report.

Procedure: On November 3, 2005, the entire meeting is open to the public. On November 4, 2005, from 8 a.m. to 2:15 p.m. the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 25, 2005. Oral presentations from the public will be scheduled on November 3, 2005, between approximately 2 p.m. and 3:45 p.m. and on November 4, 2005, between 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 4, 2005, from 2:15 p.m. to 3 p.m., the meeting will be closed to permit discussion where disclosure

would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)), and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss a subcommittee's report of the internal research programs in the Office of Blood Research and Review, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 6, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05-20560 Filed 10-13-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held November 8, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-

7001, FAX: 301-827-6776, e-mail: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading "Oncologic Drugs Advisory Committee (ODAC)." (Click on the year 2005 and scroll down to ODAC meetings.)

Agenda: The committee will discuss new drug applications approved under 21 CFR 314.500 and 601.40 (subparts H and subpart E, respectively, accelerated approval regulations) in an open session to do the following: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. The committee will discuss phase IV commitments of: (1) new drug application (NDA) 50-718, DOXIL (doxorubicin hydrochloride liposome injection, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of acquired immune deficiency syndrome (AIDS) related Kaposi's sarcoma in patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) NDA 20-221/S-002, ETHYOL for injection (amifostine, MedImmune Oncology, Inc.) for reducing the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced nonsmall cell lung cancer; (3) biologics license application (BLA) 103767/0, ONTAK (denileukin diftitox, Seragen Incorporated) for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the interleukin-2 receptor; (4) NDA 21-041, DEPOCYT (cytarabine liposome injection, SkyePharma Inc.) for the intrathecal treatment of lymphomatous meningitis; and (5) NDA 21-156, CELEBREX (celecoxib capsules, Pfizer, Inc.) for reducing the number of adenomatous colorectal polyps in familial adenomatous polyposis, as an adjunct to usual care (e.g., endoscopic surveillance, surgery); (6) NDA 21-174, MYLOTARG (gemtuzumab ozogamicin for injection, Wyeth Pharmaceuticals, Inc.) for the treatment of patients with CD33 positive acute myeloid leukemia