

Dated: February 8, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10115, CMS-2552 and CMS-R-148]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 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:** Federal Funding of Emergency Health Services (Section 1011); Enrollment Application; **Use:** These information collections will allow hospitals and other providers to enroll to receive payment for Section 1011 claim submissions. Section 1011 provides \$250 million per year for fiscal years 2005-2008 for payments to eligible providers for emergency health services provided to undocumented aliens and other specified aliens; **Form Number:** CMS-10115 (OMB#: 0938-0929); **Frequency:** Other: as needed; **Affected Public:** Business or other for-profit, Not-for-profit institutions, and State, local or tribal govt.; **Number of Respondents:** 62,500; **Total Annual**

Responses: 62,500; **Total Annual Hours:** 31,250.

2. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Hospital and Health Care Complexes Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24; **Use:** This form is completed by Hospitals and Health Care Complexes participating in the Medicare program. Hospitals and Health Care Complexes use this form to report the health care costs for services they provide. The information reported on this form is used by CMS to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. The revisions to this form contain the provisions for implementing section 422 of the MMA. Section 422 deals with the calculation of GME and IME payments for redistribution of unused resident slots; **Form Number:** CMS-2552-96 (OMB# 0938-0050); **Frequency:** Annually; **Affected Public:** Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; **Number of Respondents:** 6,111; **Total Annual Responses:** 6,111; **Total Annual Hours:** 4,046,782.

3. Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; **Title of Information Collection:** Limitations on Provider Related Donations and Health Care Related Taxes; Limitation on payments to Disproportionate Share Hospitals; Medicaid and Supporting Regulations in 42 CFR 433.68, 433.74, and 447.272; **Use:** This information collection is necessary to ensure compliance with Sections 1903 and 1923 of the Social Security Act for the purpose of preventing payment of federal financial participation on amounts prohibited by the statute. State Medicaid agencies must report quarterly on the source of provider related donations received by the State or unit of local government, and health care related taxes collected. Failure to collect the funding data on a quarterly basis may result in Federal funds not being returned promptly and properly to the Federal Government; **Form Number:** CMS-R-148 (OMB#: 0938-0618); **Frequency:** Quarterly and as needed; **Affected Public:** State, Local or Tribal Government; **Number of Respondents:** 50; **Total Annual Responses:** 40; **Total Annual Hours:** 3,200.

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/pa/, 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 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: February 11, 2005.

Michelle Shortt,

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

[FR Doc. 05-3127 Filed 2-17-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription 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 will be open to the public.

Name of Committee: Nonprescription 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 on March 23, 2005, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shalini Jain, 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: 301-827-6801, e-mail: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 23, 2005, the committee will discuss the microbiologic surrogate endpoints used

to demonstrate the effectiveness of antiseptic products used in health care settings. The discussion will also focus on related public health issues, trial design, and statistical issues. The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to NDAC).

Procedure: 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 March 16, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 23, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 16, 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.

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 LaNise Giles, 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: February 10, 2005.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

[FR Doc. 05-3115 Filed 2-17-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological 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). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological 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 March 15, 2005, from 8:30 a.m. to approximately 5:40 p.m.

Location: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), 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 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review safety and immunogenicity for two Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Absorbed (Tdap) vaccines. In the morning the committee will review safety and immunogenicity data for a Tdap vaccine manufactured by GlaxoSmithKline Biologicals. In the afternoon the committee will review safety and immunogenicity data for a Tdap vaccine manufactured by Aventis Pasteur Ltd.

Procedure: 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 March 8, 2005. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and approximately 4:10 p.m. and 4:40 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 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.

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 Christine Walsh or Denise Royster 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: February 10, 2005.

Sheila Dearybury Walcott,

Associate Commissioner for External Relations.

[FR Doc. 05-3180 Filed 2-17-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0043]

Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy; Draft Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for FDA staff and industry entitled "Compliance Policy Guide (CPG) Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23)." This draft CPG provides guidance concerning accuracy and exhaust rate criteria for sphygmomanometers. This draft guidance is being issued for public comment only and will not be implemented until a final CPG is announced in the **Federal Register**.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FAX your request to 240-632-6861. Submit written comments on the draft 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