

The burden is based on the number of applications received in the last 3 years.

Dated: November 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-19285 Filed 11-14-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on December 14, 2006, from 8 a.m. to 6 p.m. and on December 15, 2006, from 8 a.m. to 5 p.m.

Location: Crowne Plaza/Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301-589-0800.

Contact Person: Sohail Mosaddegh, 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: sohail.mosaddegh@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), codes 3014512530 or 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committee will discuss the overall benefit to risk considerations for the approved product KETEK (telithromycin), new drug application (NDA) 21-144, with the current indications of: Acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia, manufactured by Sanofi-Aventis.

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 headings Anti-Infective Drugs Advisory Committee or Drug Safety and Risk Management Advisory Committee. (Click on the year 2006 and scroll down to the above named committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before November 30, 2006. Oral presentations from the public will be scheduled between approximately 10 a.m. to 11 a.m. on December 15, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 30, 2006.

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 Sohail Mosaddegh 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: November 8, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6-19249 Filed 11-14-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0414]

Psychopharmacologic 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:

Psychopharmacologic 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 December 13, 2006, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2006N-0414 Suicidality data from Adult Antidepressant Trials" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on December 1, 2006. All comments received will be posted without change, including any personal information provided. Comments received on or before December 1, 2006, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring, The Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Cicely Reese, 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:

Cicely.Reese@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. 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 "Psychopharmacologic Drugs Advisory Committee (PDAC)." (Click on year 2006 and scroll down to PDAC meetings).

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 on or before November 21, 2006. Oral presentations from the public will be scheduled between approximately 10 a.m. and 12 noon. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 21, 2006. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 27, 2006.

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 Cicely Reese 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: November 1, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6-19248 Filed 11-14-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; amended at 67 FR 46519, July 15, 2002; 68 FR 787-793, January 7, 2003, 68 FR 64357-64358, November 13, 2003; at 69 FR 56433-56434, September 21, 2004;

70 FR 61293-61294, October 21, 2005; and last amended at 71 FR 46237-46238, August 11, 2006).

This notice reflects changes to the organization and functions of the Office of the Administrator (RA), Office of Rural Health Policy (RH) and the Bureau of Primary Health Care (RC).

Specifically, it moves the Intergovernmental Affairs function within the Office of Communication (RA6) from the Office of Administrator (OA) to the Office of Rural Health Policy (RH). Additionally, it moves the Black Lung Clinic Program and the Radiation Exposure Screening and Education Program from the Bureau of Primary Health Care (RC) to the Office of Rural Health Policy (RH).

Chapter RA—Office of the Administrator

Section RA-10, Organization

The Offices under the Immediate Office of the Administrator consist of the following components:

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Equal Opportunity and Civil Rights (RA2);
- (3) Office of Planning and Evaluation (RA5);
- (4) Office of Communications (RA6);
- (5) Office of Minority Health and Health Disparities (RA9);
- (6) Office of Legislation (RAE);
- (7) Office of Information Technology (RAG); and
- (8) Office of International Health Affairs (RAH).

Section RA-20, Functions

Delete the functional statement for the Office of Communications (RA6) in its entirety and replace it with the following:

Office of Communication (RA6)

Provides leadership and general policy and program direction for, and conducts and coordinates communications and public affairs activities of the Agency. Specifically: (1) Serves as focal point for coordination of Agency communications activities with those of other health agencies within the Department of Health and Human Services and with field, State, local, voluntary and professional organizations; (2) develops and implements national communications initiatives to inform and educate the public, health care professionals, policy makers and the media; (3) coordinates, researches, writes and prepares speeches and audiovisual presentations for the HRSA Administrator and staff; (4) provides communication and public

affairs expertise and staff advice and support to the Administrator in program and policy formulations and execution consistent with policy direction established by the Assistant Secretary for Public Affairs; (5) develops and implements policies and procedures related to external media relations and internal employee communications including those for the development, review, processing, quality control, and dissemination of Agency communications materials, including exhibits and those disseminated electronically; (6) serves as Communications and Public Affairs Officer for the Agency including establishment and maintenance of productive relationships with the news media; (7) coordinates the implementation of the Freedom of Information Act for the Agency; and (8) manages audio visual and multimedia activities in support of communications efforts through multiple media formats.

Chapter RH—Office of Rural Health Policy

Section RH-10, Organization

The Office of Rural Health Policy is headed by the Associate Administrator who reports directly to the Administrator, HRSA. Specifically, this notice amends the functional statement by adding responsibility for the Black Lung Clinic Program; Radiation Exposure Screening and Education Program, and Intergovernmental Affairs.

Section RH-20, Functions

Delete the functional statement for the former Rural Health Policy (RH) in its entirety and replace with the following:

The Office of Rural Health Policy (RH) serves as a focal point within the Department and as a principal source of advice to the Administrator and Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the Nation's rural areas and border areas, providing leadership and interacting with stakeholders in the delivery of health care to underserved and at risk populations. Specifically, the Office of Rural Health Policy is organized around the following primary issue areas:

Delivery of Health Services: (1) Collects and analyzes information regarding the special problems of rural health care providers and populations; (2) works with States, State hospital associations, private associations, foundations, and other organizations to focus attention on, and promote solutions to problems related to the delivery of health services in rural communities; (3) provides staff support