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