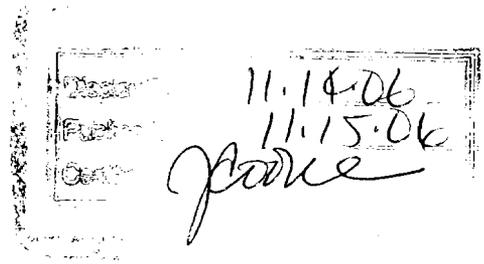


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

*Pub*



**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.

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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](mailto: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.)

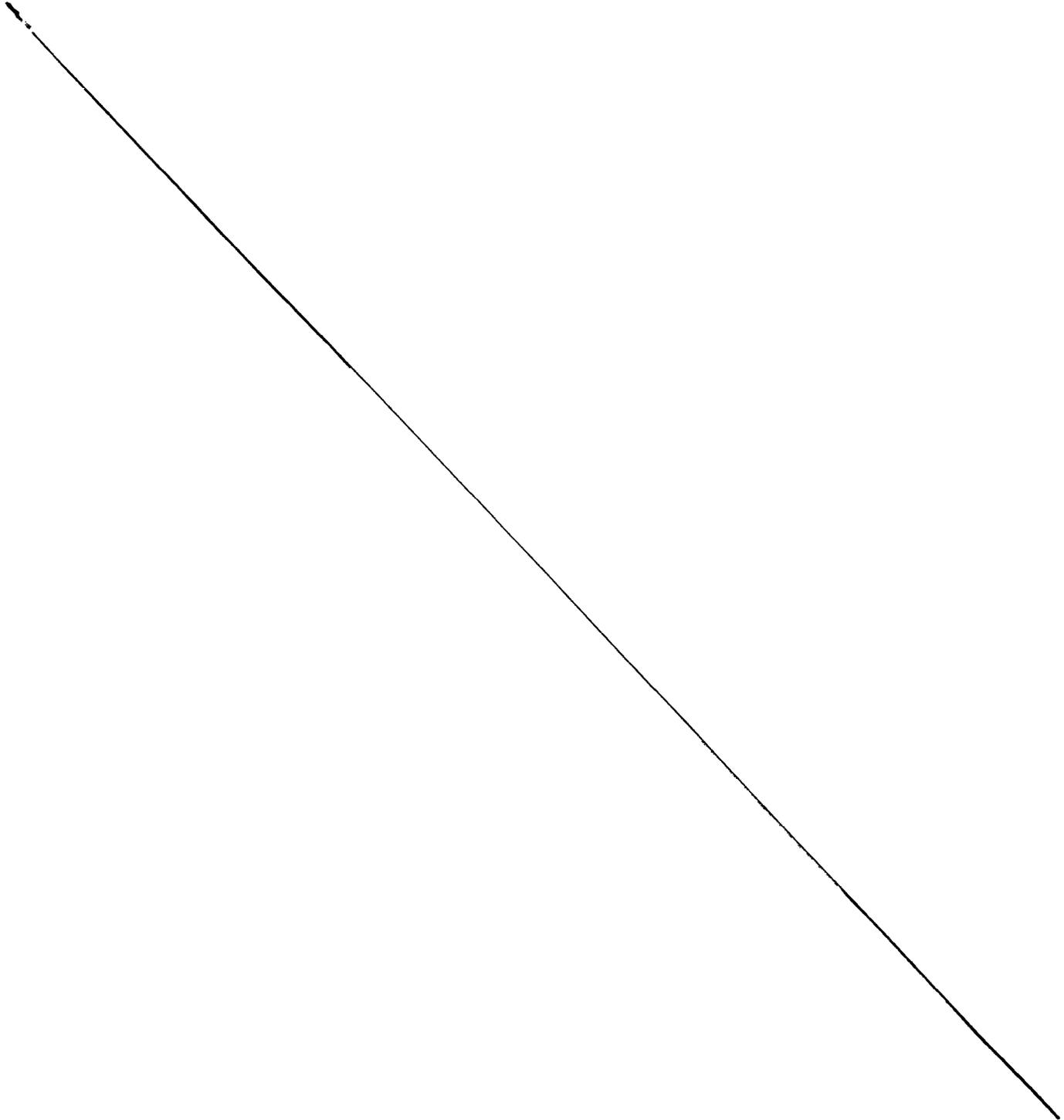
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before November 30, 2006. Oral presentations from the public will be scheduled between approximately 10 a.m. 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: \_\_\_\_\_

11/8/06  
November 8, 2006.

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Randall W. Lutter,  
Associate Commissioner for Policy and Planning.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

**BILLING CODE 4160-01-S**

