

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### Anti-Infective Drugs 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 Committee:* Anti-Infective 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 January 8, 2003, from 8 a.m. to 5 p.m., and on January 9, 2003, from 9 a.m. to 5 p.m.

*Location:* Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

*Contact Person:* Tara P. Turner, 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, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On January 8, 2003, the committee will discuss new drug application (NDA) 21-144, KETEK (telithromycin), Aventis Pharmaceuticals, Inc., proposed for treatment of community-acquired pneumonia, acute exacerbation of chronic bronchitis, and acute maxillary sinusitis. On January 9, 2003, the committee will discuss issues pertaining to the contents in the document entitled "Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine

(Appendix A of the “Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern”) (see the FDA Internet site at: <http://www.fda.gov/cvm/guidance/dguide152.doc>) as it relates to the process for evaluating antimicrobial resistance concerns for the Center for Veterinary Medicine’s preapproval safety evaluation of a new animal drug.

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 December 31, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on January 8, 2003, and between approximately 1 p.m. and 2 p.m. on January 9, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 31, 2002, 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 Tara P. Turner 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: December 4, 2002.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

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