

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

OMB

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Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed 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 April 26, 2001, 8 a.m. to 6 p.m., and on April 27, 2001, 8:30 a.m. to 12 noon.

Location: Holiday Inn, The Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

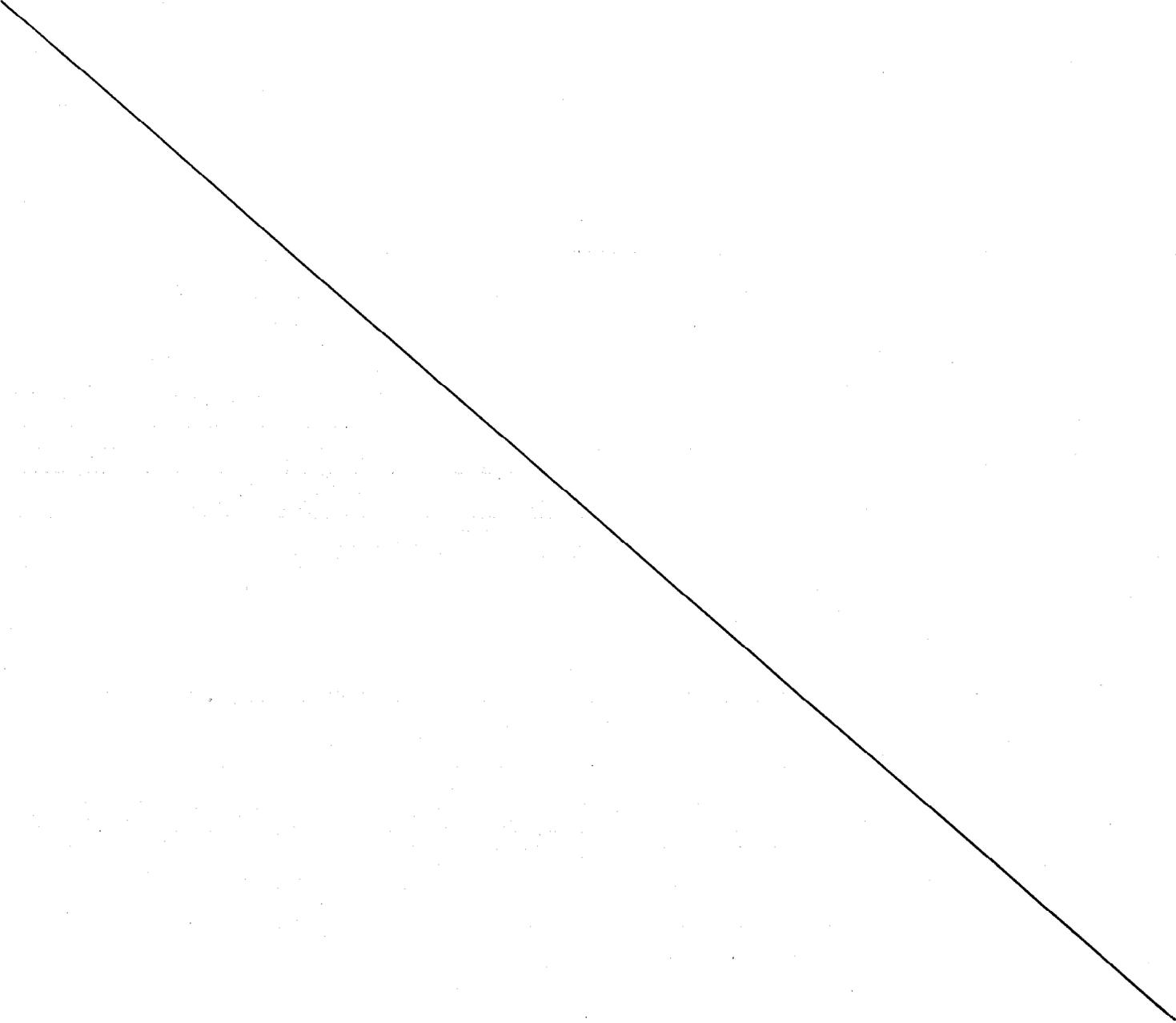
Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 26, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21-144, Ketek™ (telithromycin) tablets, Aventis Pharmaceuticals, Inc., for the treatment of bacterial respiratory infections.

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 April 18, 2001. Oral presentations from the public will be scheduled on April 26, 2001, between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 18, 2001, 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.

Closed Committee Deliberations: On April 27, 2001, from 8:30 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

MAR 22 2001

Dated: _____

March 22, 2001



Linda A. Suydam
Senior Associate Commissioner

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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