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.

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 29, 2001, 8 a.m. to 6 p.m. and January 30, 2001, 8 a.m. to 4:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: 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 January 29, 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 community-acquired pneumonia, acute exacerbation of chronic bronchitis, acute sinusitis, and tonsillitis/pharyngitis. On January 30, 2001, the committee will consider the safety and efficacy of NDA 50–755, Augmentin ES™ (amoxicillin/clavulanate) 90 milligrams per kilogram per day, SmithKline Beecham Pharmaceuticals, for the treatment of pediatric patients with acute otitis media due to penicillin resistant *Streptococcus pneumoniae*.

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 January 22, 2001. Oral presentations from the public will be scheduled on January 29, 2001, between approximately 2 p.m. and 3 p.m., and on January 30, 2001, between approximately 2:45 p.m. to 3:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 22, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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: Antiviral 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 11, 2001, 8:30 a.m. to 5:30 p.m. Interested persons and organizations may submit written comments by January 8, 2001, to the Dockets Management Branch (address below).

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: Presentations and committee discussions will focus on clinical trial design issues for patients with human immunodeficiency virus (HIV–1) infection who have limited therapeutic options (treatment sometimes referred to as ''salvage'' therapy). This meeting is being convened in response to the recognized difficulty in evaluating the safety and effectiveness of new antiretroviral therapeutics in heavily pretreated patients. A further goal of this meeting is to facilitate and promote the development of new therapies for patients who are most in need of new therapeutic options.

For the purpose of this meeting, we will define ''salvage'' therapy as regimens that follow a loss or lack of virologic response to at least two previous antiretroviral regimens that, in total, have consisted of drugs from all of the approved drug classes (protease inhibitors, nucleoside and non-nucleoside reverse transcriptase inhibitors). This population of heavily pretreated patients reflects a population for whom selection of active controls in clinical trials is a particular challenge.

The primary objectives for the committee deliberations are to discuss issues relating to the identification of appropriate control arms, possible trial designs, and study endpoints for this patient population. In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing the following types of relevant data, information, and views:

1. Proposals for trial designs, including comments and suggestions on the following:

- The role of intensification trials, concentration controlled trials, historical-controlled trials, dose-response trials, and factorial comparisons using multiple investigational agents;
- Blinded versus open label trials;
- Study duration or duration of blinded treatment; and
- Pertinent statistical considerations for different trial design options.

2. Comments relating to patient population inclusion criteria and suggestions for baseline stratification characteristics (such as treatment history, resistance testing, CDC classification or others).

3. Proposals and comments regarding appropriate control arms and the role of resistance testing for constructing treatment regimens.

4. Comments on appropriate outcome measures such as virologic and/or