

## 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.

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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:* 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 August 6 and 7, 2002, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, 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 12531. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On August 6, 2002, the committee will discuss new drug application (NDA) 21-449, adefovir dipivoxil tablets, Gilead Sciences, Inc., proposed for treatment of chronic hepatitis B infection (HBV). On August 7,

2002, the committee will discuss clinical trial design issues in the development of products for the treatment of chronic hepatitis B infection.

*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 July 30, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 30, 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 Turner at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the August 6 and 7, 2002, Antiviral Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Antiviral Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: July 18, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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