

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DHR

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Certifier	[Signature]

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 10, 2001, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

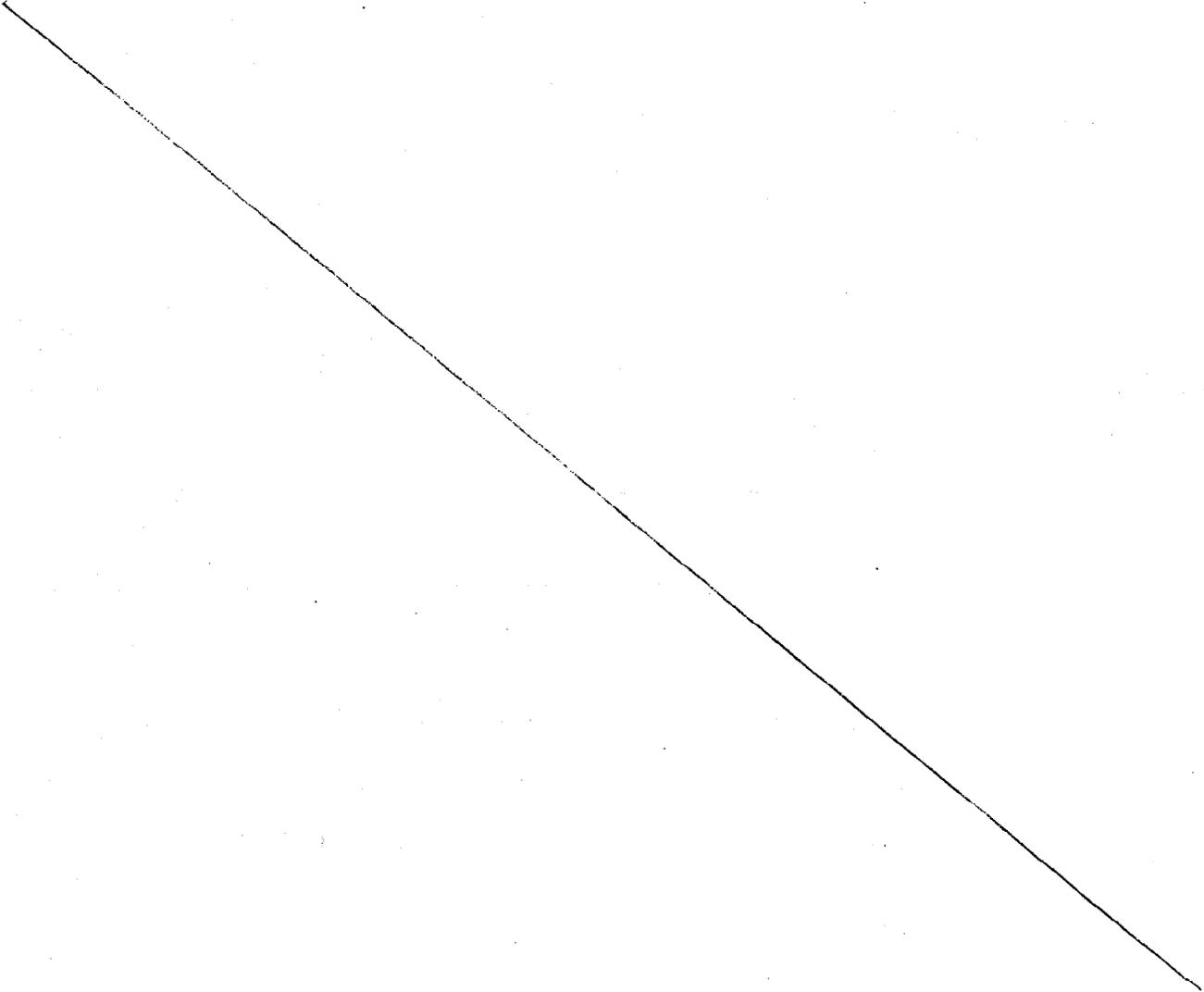
Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21-227, Cancidas™ (caspofungin) Injection, Merck Research Laboratories, indicated for treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies.

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 4, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make

formal oral presentations should notify the contact person before January 4, 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.

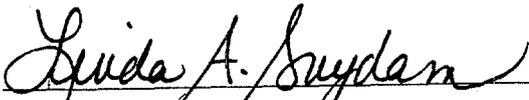
FDA regrets that it was unable to publish this notice 15 days prior to the January 10, 2001, meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Antiviral Drugs Advisory Committee were available at this time, the Commissioner 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.

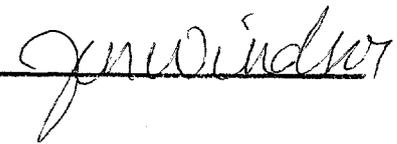
2).

Dated: December 18, 2000.



Linda A. Saydam,
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



J. W. Windsor

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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