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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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). At least one portion of the meeting will be closed 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 July 25, 2000, 8:30 a.m. to 5 p.m. and on July 26, 2000, 8:30 a.m. to 5 p.m.

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

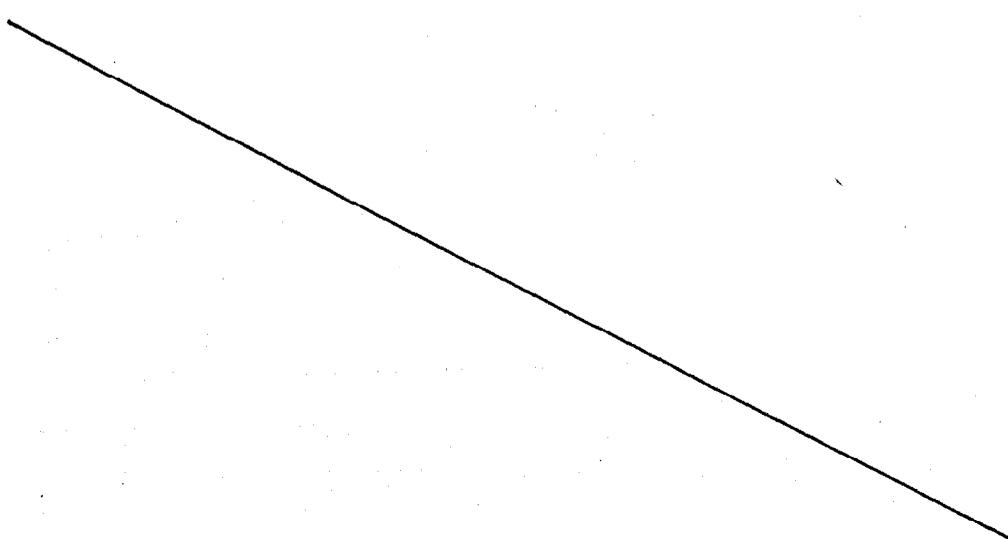
Contact Person: Nancy Chamberlin or Beverly O'Neil, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or by e-mail: CHAMBERLINN@CDER.FDA.GOV, or FDA Advisory Committee 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 July 25, 2000, the committee will discuss scientific data characterizing relationships of pharmacokinetic parameters and virologic response to approved antiretroviral drugs used in the treatment of human immunodeficiency virus (HIV) infection. The primary objectives for the committee deliberations are to explore the use of pharmacokinetic data to improve the evaluation of new formulations, alternative dosing regimens, and choice of dosing in the setting

of drug-drug interactions for approved antiretroviral drugs. Additionally, other issues to be discussed include: the relationship between pharmacokinetic parameters and drug toxicity, and safety requirements and pediatric considerations for alternative dosing regimens.

Procedure: On July 25, 2000, from 8:30 a.m. to 5 p.m., the meeting is open to the public. 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 11, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. on July 25, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2000, 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 July 26, 2000, from 8:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). Pending investigational new drug applications and drug development plans will be presented, and recent action on selected new drug applications will be discussed. This portion of the meeting will be closed to permit discussion of this information.



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

2).

Dated: 6/19/00

Linda A. Suydam

Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

J. Windsor

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

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