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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2670]

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.

Dates and Time: The meeting will be held on November 2 and 3, 1999, from 8:30 a.m. to 5 p.m. Interested persons and organizations may submit written comments by September 30, 1999, to the Dockets Management Branch (address below).

Location and Addresses: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, 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: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research, (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or the 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 address issues related to testing for development of resistant human immunodeficiency virus (HIV-1), with an emphasis on its potential

role in antiretroviral drug development. The primary objectives of these deliberations are to obtain advisory committee recommendations on the amount and type of resistance data needed to support both preclinical and clinical development of antiretroviral drugs and product labeling. This 2-day meeting will explore the following scientific issues: (1) Performance characteristics of genotypic and phenotypic assays, (2) definitions of antiviral drug resistance, (3) relationships between the development of mutations or reduced susceptibility and treatment outcome, and (4) available evidence supporting the clinical utility of testing for the development of antiviral drug resistance. 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:

- Pre-clinical and/or clinical trial data on the relationship between the development of HIV mutations and changes in susceptibility to antiviral therapies.
- Prospective or retrospective clinical trial data on the relationship between genotype and/or phenotype and treatment outcome.
- Proposals for incorporating HIV resistance testing in clinical trial design.
- Proposals for utilizing information derived from HIV resistance testing to support product labeling.

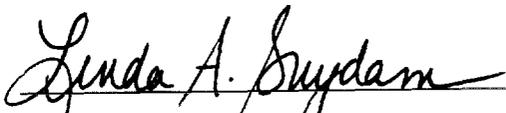
These submissions should contain the following docket number, 99N-2670, and should be made to the Dockets Management Branch address provided previously in this document.

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 October 27, 1999. Oral presentation from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 3, 1999. Time allotted for each presentation may be limited. Written submissions may be made to the contact person by October 27, 1999. Those desiring to make formal oral presentations should notify the contact person before October 27, 1999, 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: August 13, 1999



Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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