

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SMB

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Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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: Pediatric Subcommittee of the 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 April 23, 2001, 8 a.m. to 5:30 p.m. and on April 24, 2001, 8 a.m. to 3 p.m.

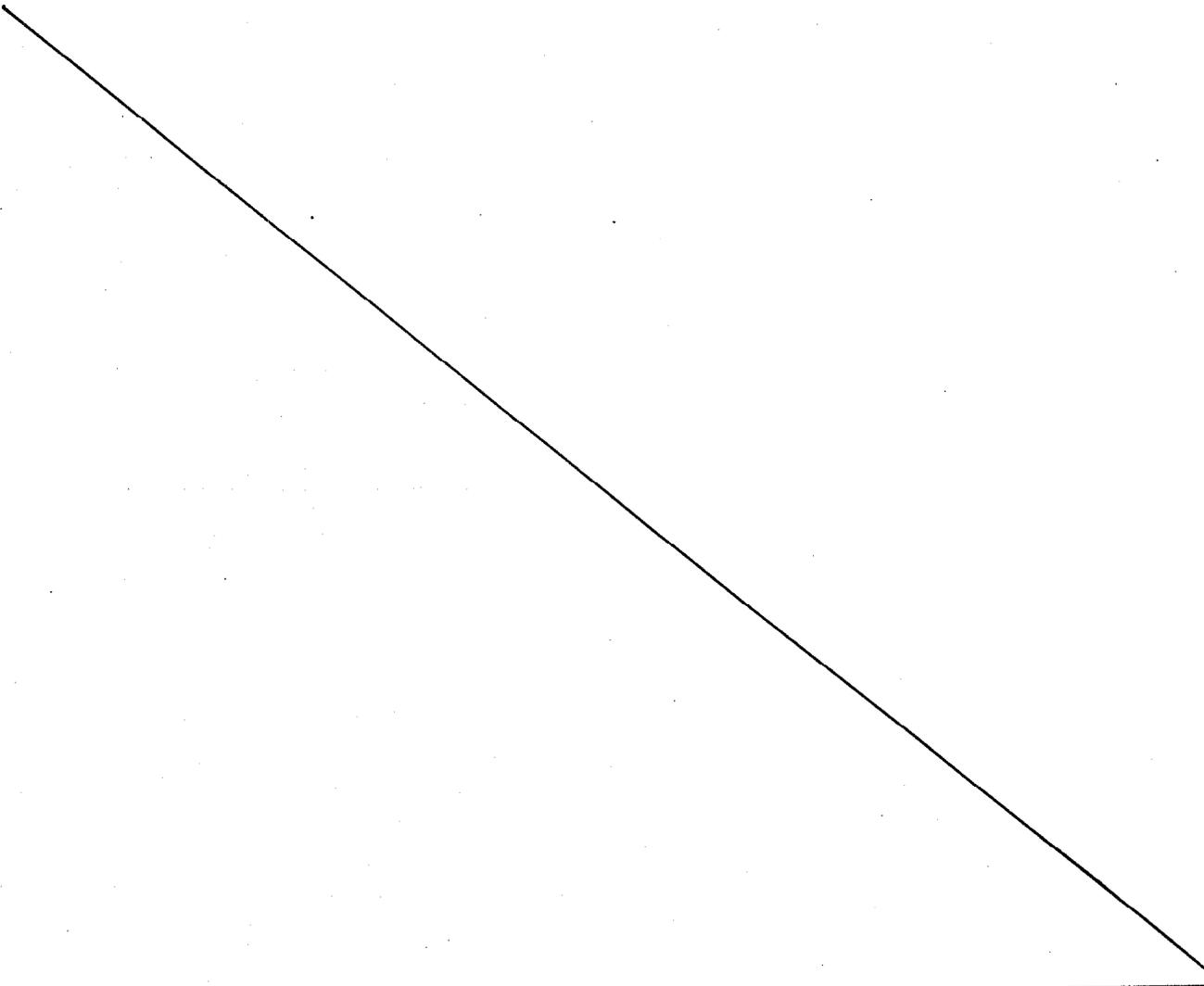
Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD 20857.

Contact: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: petersonj@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 April 23, 2001, beginning at 8 a.m., the subcommittee will discuss issues in drug development for pediatric patients with chronic hepatitis C. Beginning at 3:30 p.m., the agency will provide an update to the subcommittee as to recent efforts to ensure adequate labeling and proper pediatric use of therapies. On April 24, 2001, the subcommittee will discuss issues involved

in designing clinical trials to study anti-muscarinics for drooling in children with cerebral palsy and other neurologic diseases, as well as the ethical issues involved in performing studies with children having special needs.

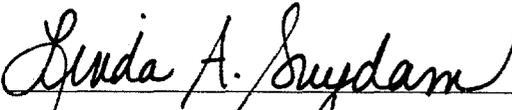
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 13, 2001. On April 23 and 24, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 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: March 16, 2001.

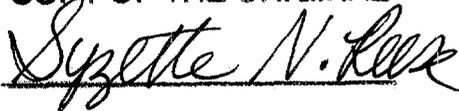


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Suzette N. Rose