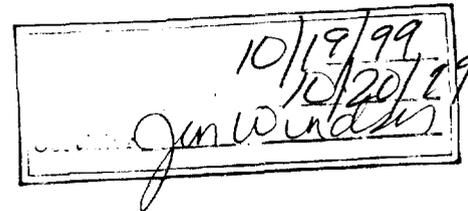


DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4236]

**Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee;
Notice of Meeting; Request for Comments**

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: Pediatric Advisory 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 November 15, 1999, from 8 a.m. to 5:30 p.m., and on November 16, 1999, from 8 a.m. to 1 p.m. Interested persons and organizations may submit written comments by November 8, 1999, to the Dockets Management Branch (address below).

Location and Addresses: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Contact: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6767, 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.

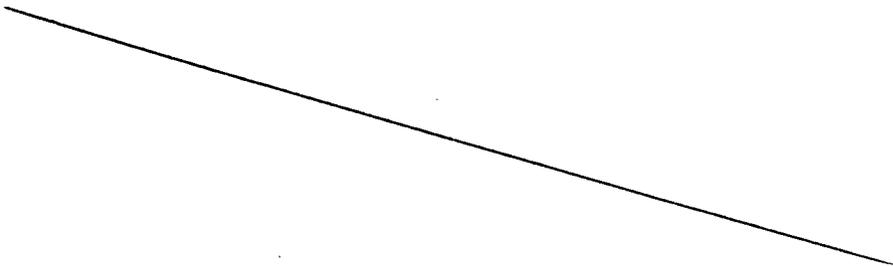
Agenda: The subcommittee will discuss broad pediatric issues as recommended in the final rule entitled "Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biologic Products in Pediatric Patients" (63 FR 66632, December 2, 1998).

On November 15, 1999, the subcommittee will discuss ethical considerations in the conduct of pediatric clinical trials involving a drug or biologic product, specifically the role of pediatric subjects/volunteers who do not have the disease under study.

On November 16, 1999, the subcommittee will discuss whether or not there is a public health need for the pharmaceutical industry to extend their drug development program for sleep disorders into the pediatric population.

In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing data, information, and views relevant to the agenda items. These submissions should contain the docket number 99N-4236 and be submitted to the Dockets Management Branch (address above).

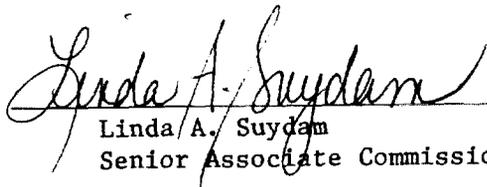
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 8, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on November 15, 1999, and between approximately 10:30 a.m. and 11 a.m. on November 16, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 8, 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.

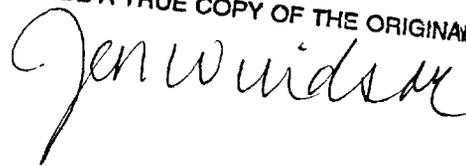
2).

Dated: October 12, 1999



Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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

BILLING CODE 4160-01-F