

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Pediatric Subcommittee of the Anti-Infective 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: 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 June 9, 2004, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez, 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: perezth@cder.fda.gov. Please call the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512530, for up-to-date information on this meeting.

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Agenda: The subcommittee will meet between 8 a.m. and 1:30 p.m., and the agency will report to the committee on adverse event reporting as mandated in section 17 of the Best Pharmaceuticals for Children Act. The products to be discussed during this portion of the meeting include HYCAMTIN (topotecan), TEMODAR (temozolomide), EFFEXOR (venlafaxine), MONOPRIL (fosinopril), ALLEGRA (fexofenadine), DURAGESIC (fentanyl), CILOXAN (ciprofloxacin), and VIGAMOX (moxifloxacin). Following this, from approximately 1:30 p.m. to 3:30 p.m., the agency will provide an update on neonatal withdrawal syndrome and congenital eye malformations reported in infants whose mothers used selective serotonin reuptake inhibitors (SSRIs) during pregnancy. From approximately 3:30 p.m. to 4 p.m., the agency will provide an overview of the Pediatric Research Equity Act, which was signed into law on December 3, 2003. From 4 p.m. to 4:30 p.m., there will be an overview of the Institute of Medicine report entitled "Ethical Conduct in Pediatric Clinical Trials." Finally, from 4:30 p.m. to 4:45 p.m., the agency will provide an update on the subpart D, institutional review board referral process.

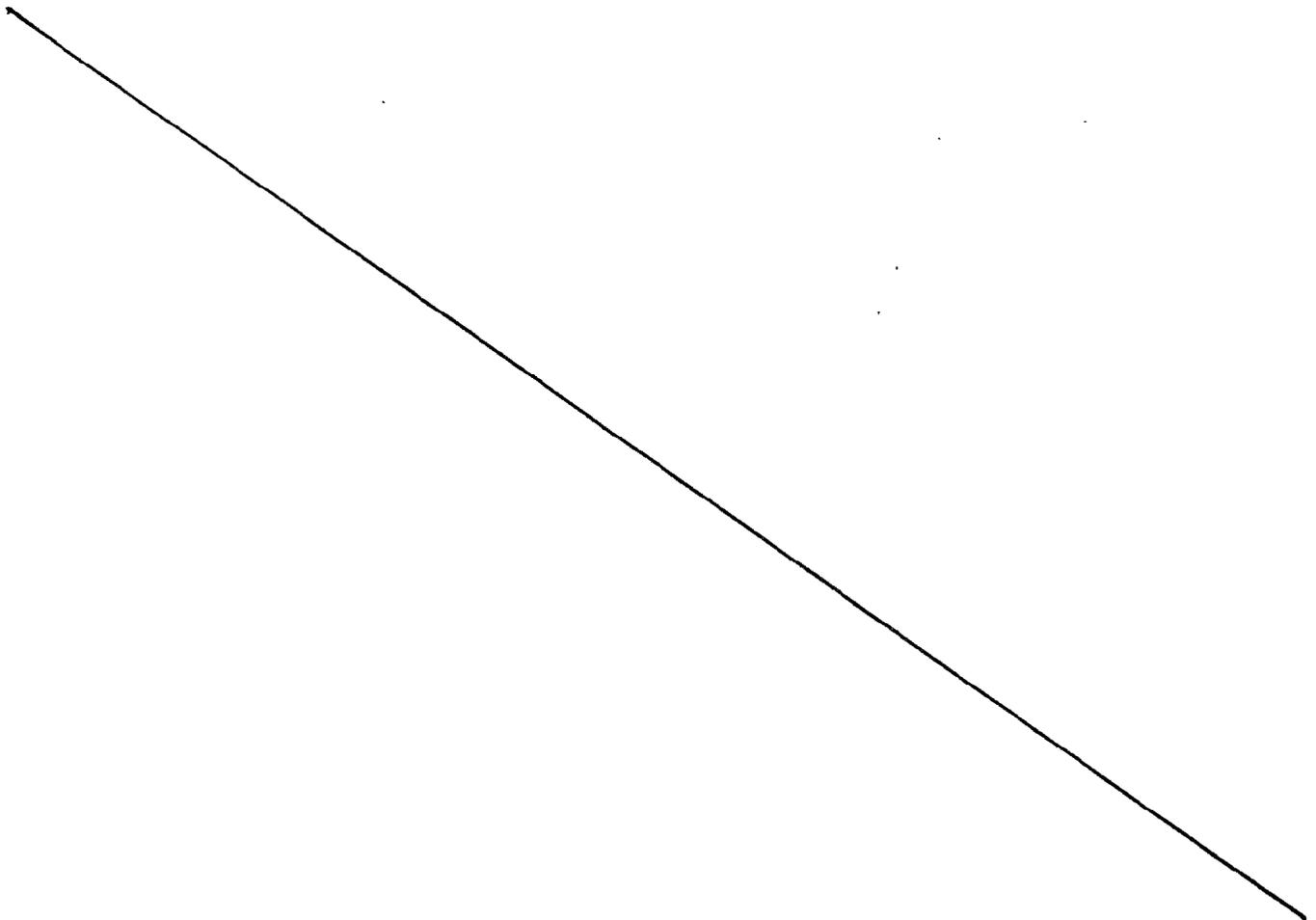
The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

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 June 1, 2004. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m., for issues related to the section 17 adverse event reports. Also, oral presentations from the public will be scheduled between approximately 3 p.m. and 3:30 p.m., for issues related to neonatal withdrawal

syndrome and congenital eye malformations seen in infants. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by June 1, 2004, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas Perez at least 7 days in advance of the meeting.

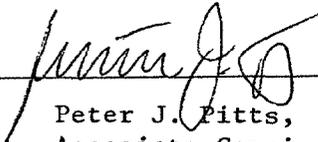


Notice of this meeting is given under the Federal Advisory Committee Act

(5 U.S.C. app. 2).

Dated: 5/5/04
May 5, 2004.

B Bodo 5-7-04


Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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