DMB
Display Date 1-9-04
Publication Date 1-12-04
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 Subcommittee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 3, 2004, from 9 a.m. to 4:45 p.m., and February 4, 2004, from 8 a.m. to 12 noon.

Location: CDER 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: *perezt@cder.fda.gov*. Please call the FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530, for up-to-date information on this meeting.

oc03401

4021

NM 1

Agenda: On February 3, 2004, the subcommittee will meet between 9 a.m. and 10:15 a.m., and the agency will report to the subcommittee on Adverse Event Reporting as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA). The products to be reported during this portion of the meeting include: Paxil (paroxetine), Celexa (citalopram), Pravachol (pravastatin), and Navelbine (vinorelbine). Following this, from approximately 10:30 a.m. to 4:45 p.m., the subcommittee will discuss the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population.

On February 4, 2004, the subcommittee will meet between 8 a.m. and 12 noon to continue the discussion on the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population.

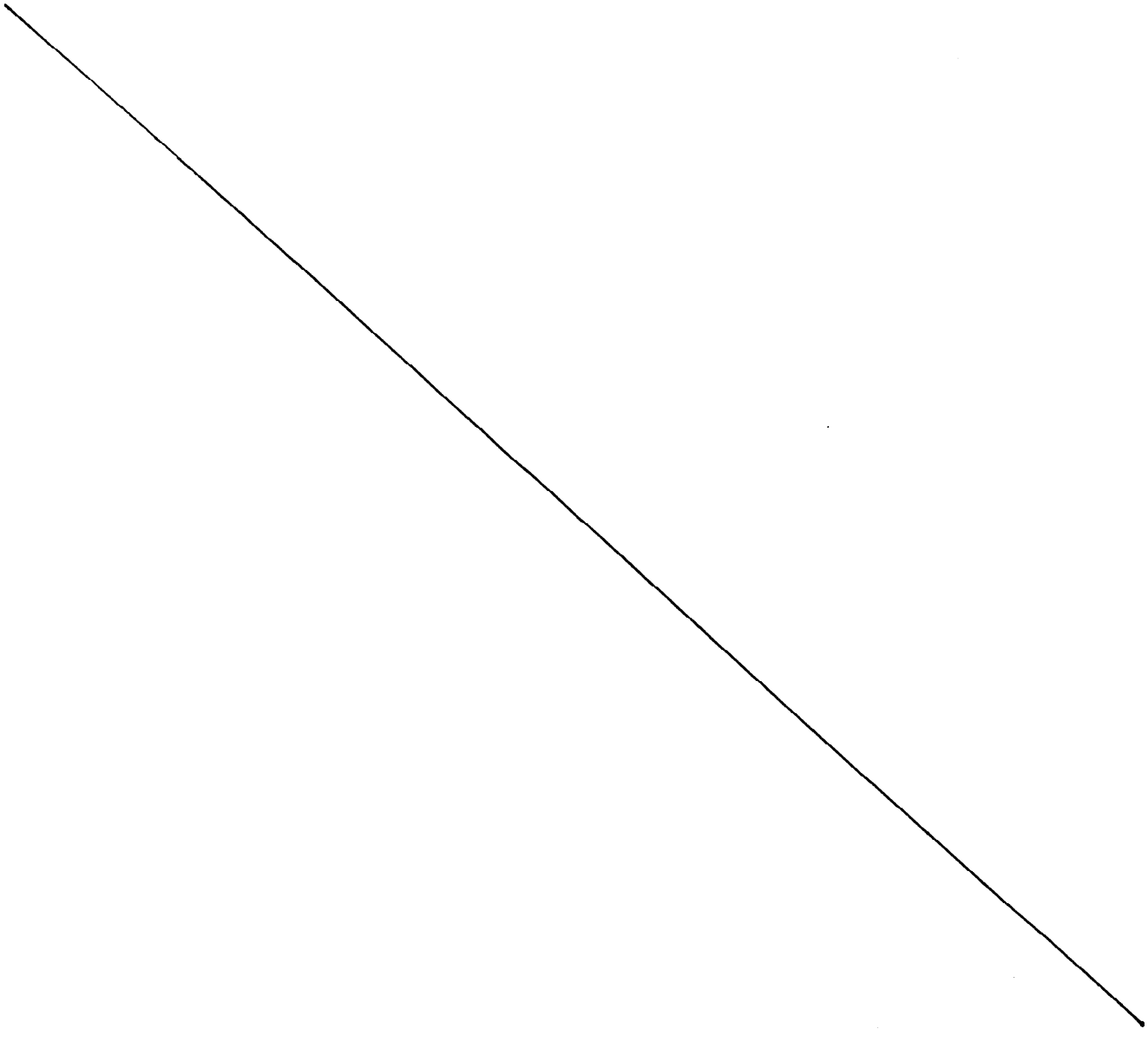
The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at *www.fda.gov/ohrms/dockets/ac/menu.htm.*

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 January 23, 2004. On February 3, 2004, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. for issues related to the Section 17 adverse event reports. Also, on February 3, 2004, oral presentations from the public will be scheduled between approximately 3:45 p.m. and 4:45 p.m. for issues related to cardiac imaging in pediatric patients. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by January 23, 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 notify 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: 1/5/04

January 5, 2004.

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S

NOTICES-FINAL GUIDANCES		
Edit Display Only	**Docket No. 2000D-1314, OC 2003378. Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes. [PRE-PUB]**	Delete
NOTICES		
Edit Display Only	**Docket No. 2003N-0328, OC 2003374. Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter. [PRE-PUB]** N 2 **Supporting Statement Word Version** **Supporting Statement PDF Version**	Delete
Edit Display Only	**Docket No. 2003N-0509, OC 2003389. Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Health Claim Disclaimers on Foods. [PRE-PUB] OMB approval no. 0910-0531 expires June 30, 2004** NAL 1	Delete
CFR CORRECTION		
Edit Display Only	**Docket No. 1980N-0208, CBER 999999. Biological Products; Bacterial Vaccines and Toxolda; Implementation of Efficacy Review; Correction. [FR Doc. C3-32255] [PRE-PUB]**	Delete

Federal Register Notices Publishing on January 8, 2004

Volume 69 Table of Contents