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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 10-7-03  
Publication Date 10-8-03  
Certifier COOLE

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.

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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 October 29, 2003, from 8 a.m. to 5:30 p.m. and October 30, 2003, from 8 a.m. to 3:30 p.m.

*Location:* Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301-556-2046.

*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, e-mail: [perezth@cder.fda.gov](mailto:perezth@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.

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*Agenda:* On October 29, 2003, the subcommittee will meet between 8 a.m. and 3:30 p.m., to discuss the risk assessment and possible risk management strategies for hypothalamic pituitary adrenal (HPA) axis suppression in children who are treated for skin disorders with topical corticosteroids. Following this, from approximately 3:45 p.m. to 5:30 p.m., 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 discussed during this portion of the meeting include ZYRTEC (cetirizine), BUSULFEX (busulfan), COZAAR (losartan), NOLVADEX (tamoxifen), ACCUPRIL (quinapril), and SERZONE (nefazodone).

On October 30, 2003, the subcommittee will meet between 8 a.m. and 3:30 p.m., to discuss how to approach long-term monitoring for cancer occurrence among patients treated for atopic dermatitis with topical immunosuppressants.

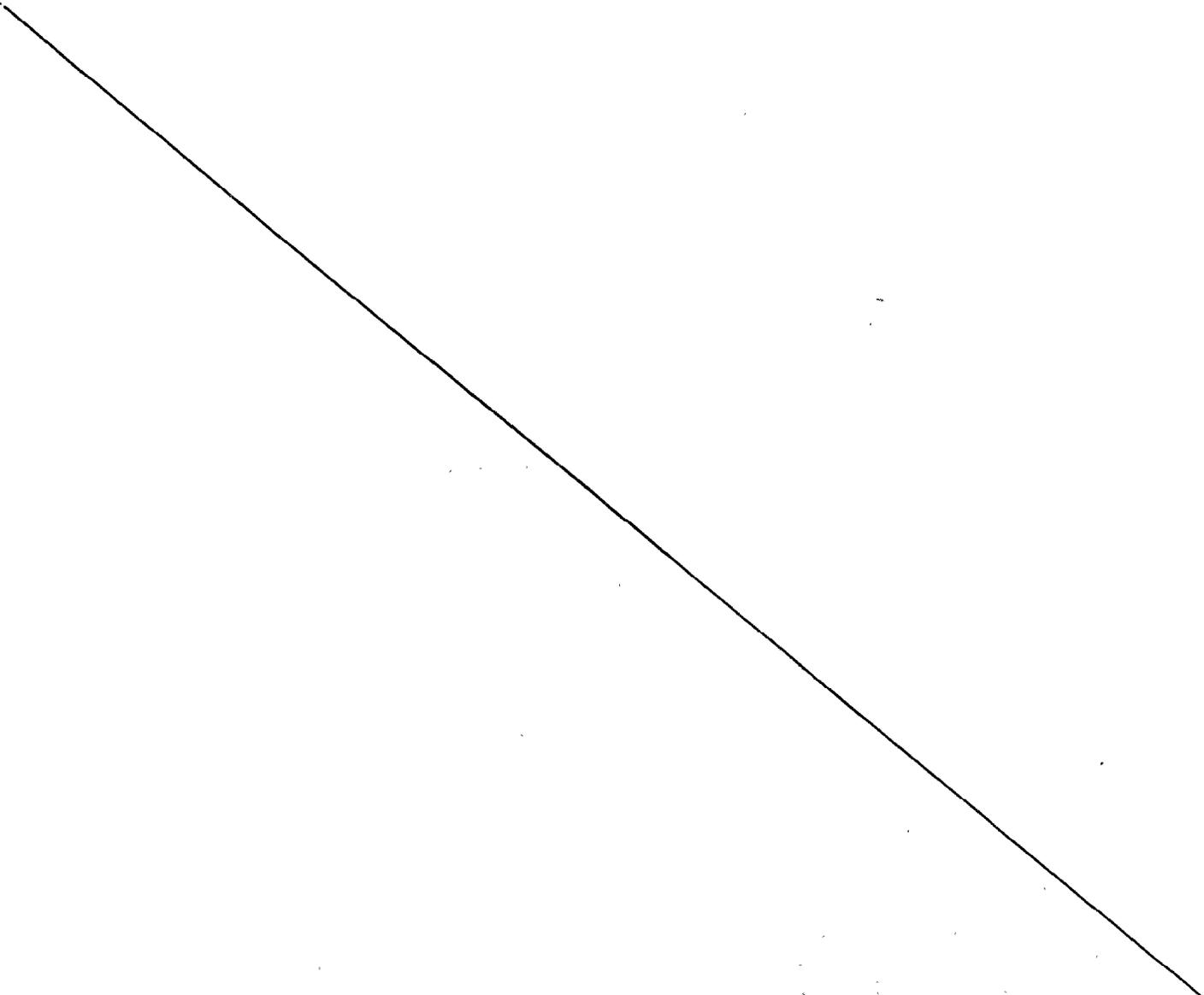
The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at [http:// www.fda.gov/ohrms/dockets/ac/menu.htm](http://www.fda.gov/ohrms/dockets/ac/menu.htm).

*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 October 21, 2003. On October 29, 2003, oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. for issues related to atopic dermatitis, and between approximately 4:30 p.m. and 5 p.m. for issues related to section 17 of the BPCA. On October 30, 2003, oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 21, 2003, 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: 10/2/03  
October 2, 2003.

  
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Peter J. Pitts,  
Associate Commissioner for External Relations.

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

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