

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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 Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Wednesday, March 22, 2006, from 8 a.m. to 6 p.m.

Location: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14C-06) Rockville, MD 20857, 301-827-6687, e-mail: Jan.Johannessen@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572

in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss a report by the agency, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), on adverse event reports possibly related to clofarabine (CLOLAR), irbesartan (AVAPRO), sibutramine (MERIDIA), and the mixed salts amphetamine product (ADDERALL). In continuation of a prior committee discussion of adverse events for the class of methylphenidate products used to treat attention deficit hyperactivity disorder (ADHD), the committee will hear and discuss neuropsychiatric adverse events possibly related to other approved ADHD medications. The presentations will focus on neuropsychiatric adverse event reports and clinical trial data from approved ADHD medications. The committee will also receive an update on efforts to better understand cardiovascular adverse events possibly related to ADHD medications.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to Pediatric Advisory Committee meetings.)

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 March 8, 2006. Oral presentations from the public will be scheduled on March 22, 2006, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by March 8, 2006, and submit a brief statement of the general

3

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 Jan N. Johannessen 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: January 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

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