

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2004N-0337]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

This notice announces a forthcoming meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA's and certain Department of Health and Human Services' (HHS) regulatory issues.

Date and Time: The meeting will be held on September 10, 2004, from 8:30 a.m. to 3:30 p.m.

Addresses: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2004 and scroll down to PAC meetings.) Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select Docket Number 2004N-0337, entitled "Subpart D IRB Referral" and follow the prompts to submit your statement. Written comments should be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Received comments may be viewed on the FDA Web site at: <http://www.fda.gov/ohrms/dockets/dockets/04n0337/04n0337.htm> or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Location: Regency Room, DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 17-51), Rockville, MD 20857, 301-827-6687, or by e-mail: jjohannessen@fda.gov. Please call the FDA Advisory Information Line, 1-800-741-8138 (301-443-0572 in the

Washington, DC area), code 8732310001, for up-to-date information on this meeting.

Agenda: On Friday, September 10, 2004, the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss a referral by an Institution Review Board (IRB) of a proposed clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by HHS. The proposed clinical investigation is entitled "Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder (ADHD): A Functional Magnetic Resonance Study." Because the proposed clinical investigation would be regulated by FDA, and conducted or supported by HHS, both FDA and the Office for Human Research Protections, HHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on ADHD, an overview of the protocol and the referring IRB's deliberations on the protocol, and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on September 15, 2004; the announcement of the September 15, 2004, meeting can be found elsewhere in this issue of the **Federal Register**.

Also elsewhere in this issue of the **Federal Register** is a document announcing a public comment period concerning whether the proposed clinical investigation should proceed. Information regarding submitting comments during that period is contained in that document.

The background materials for the subcommittee meeting will be made publicly available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2004 and scroll down to PAC meetings.)

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 August 25, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon.

Time allotted for each presentation may be limited. Those desiring to make

formal oral presentations should notify the contact person by August 25, 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 Jan Johannessen at least 7 days prior to the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-17824 Filed 7-30-04; 3:42 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2004N-0330]

Food and Drug Administration**Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the 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 Committees: Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 13, 2004, from 8 a.m. to 6:30 p.m. and on September 14, 2004, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2004N-0330—Suicidality in

Clinical Trials for Antidepressant Drugs in Pediatric Patients” and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments received by August 23, 2004, will be provided to the committee before the meeting. Comments received after August 23, 2004, will be reviewed by FDA’s decision makers.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Anuja Patel, 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, FAX: 301-827-6776, e-mail: patela@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee will discuss reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder and other psychiatric disorders. Preliminary risk data based on the classification of these adverse event reports by the pharmaceutical sponsors of these products were presented at the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held on February 2, 2004. Since that meeting, experts in pediatric suicidality, assembled by Columbia University, have independently classified these reported events, and FDA has conducted an analysis of these data. On September 13 and 14, 2004, the committees will consider the results of FDA’s analysis of these independently classified events and will consider what further regulatory action may be needed with regard to the clinical use of these products in pediatric patients. The committees will also consider further research needs to address questions on this topic.

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 Division of Dockets Management before

August 23, 2004, as previously stated (see *Addresses*). Oral presentations from the public will be scheduled between approximately 2 p.m. to 6 p.m. on September 13, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 27, 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 Anuja Patel at 301-827-7001, 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: July 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-17822 Filed 7-30-04; 3:41 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science and Food and Drug Administration

[Docket No. 2004N-0337]

Solicitation of Public Review and Comment on Research Protocol: Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study

AGENCY: Office of Public Health and Science and Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA), HHS are soliciting public review and comment on a proposed research protocol entitled “Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder (ADHD); A Functional Magnetic

Resonance Study.” The proposed research would be conducted at the National Institutes of Health (NIH) and supported by NIH’s National Institute of Mental Health (NIMH). Public review and comment are solicited regarding the proposed research protocol under the requirements of HHS and FDA regulations.

DATES: To be considered, written or electronic comments on the proposed research must be received on or before 4:30 p.m. on August 20, 2004.

ADDRESSES: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2004 and scroll down to PAC meetings.) Submit written comments to the Division of Dockets Management (HFA-305), Docket No. 2004N-0337, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be viewed on the FDA Web site at: <http://www.fda.gov/ohrms/dockets/dockets/04n0337/04n0337.htm>, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, Office for Human Research Protections, The Tower Building, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852, 301-496-7005, FAX: 301-402-2071, e-mail: Jgorey@osops.dhhs.gov; or Jan N. Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 17-51), Rockville, MD 20857, 301-827-3340, or by e-mail: jjohannessen@fda.gov.

SUPPLEMENTARY INFORMATION: All studies conducted or supported by HHS which are not otherwise exempt and which propose to involve children as subjects require Institutional Review Board (IRB) review in accordance with the provisions of HHS regulations for the protection of human subjects at 45 CFR part 46, subpart D. Under FDA’s interim final rule effective April 30, 2001 (21 CFR part 50, subpart D), FDA adopted similar regulations to provide safeguards for children enrolled in clinical investigations of FDA-regulated products. Because the proposed research, “Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study,” would be