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]

BILLING CODE 4160–01–S

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@osophs.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

conducted and supported by NIH, a component of HHS, and would be regulated by FDA, both HHS and FDA regulations apply to this proposed research.

Under HHS regulations at 45 CFR 46.407, and FDA regulations at 21 CFR 50.54, if an IRB reviewing a protocol to be conducted or supported by HHS for a clinical investigation regulated by FDA does not believe that the proposed research involving children as subjects meets the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406, and FDA regulations at 21 CFR 50.51, 50.52, or 50.53, respectively, the research may proceed only if the following conditions are met: (1) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (2) the Secretary (HHS) and the Commissioner (FDA), respectively, after consultation with experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment, determine either: (a) That the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406 under HHS regulations, and 21 CFR 50.51, 50.52, or 50.53 under FDA regulations, or (b) that the following conditions are met: (i) The research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research or clinical investigation will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and 21 CFR 50.55.

HHS has received a request on behalf of the IRB of NIMH, to review under 45 CFR 46.407 the protocol entitled ''Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study.'' The principal investigator proposes to administer a single 10-milligram dose of dextroamphetamine in conjunction with functional magnetic resonance imaging (fMRI) in healthy children and children with attention deficit hyperactivity disorder (ADHD), all between 9 and 18 years of age. Subjects of the study would include 10 children for piloting tasks; 14 healthy control children; 14 children with ADHD; 24 monozygotic twins (12 pairs), discordant for ADHD; and 24 dizygotic twins (12 pairs), discordant for ADHD.

The overall goal of the proposed study is to better understand the pathophysiology of ADHD. The three specific aims of the study are to: (1) Study brain activation patterns during response inhibition tasks in children with ADHD and in healthy controls; (2) simultaneously examine the central and behavioral effects of a single-dose of amphetamine versus placebo in the two groups; and (3) examine (using monozygotic and dizygotic twins) brain activation patterns in relation to clinical state and the degree of genetic relatedness.

The NIMH IRB determined that although the protocol was not approvable under 45 CFR 46.404, 46.405, or 46.406 because the administration of dextroamphetamine posed more than minimal risks to healthy children, the protocol was suitable for review under 45 CFR 46.407. Accordingly, the NIMH IRB forwarded the protocol to OHRP under 45 CFR 46.407. Because this clinical investigation is regulated by FDA, FDA's regulations at 21 CFR part 50, subpart D, specifically 21 CFR 50.54, apply as well.

In accordance with 45 CFR 46.407(b) and 21 CFR 50.54(b), OHRP and FDA are soliciting public review and comment on this proposed clinical investigation. In particular, comments are solicited on the following questions: (1) What are the potential benefits, if any, to the subjects and to children in general; (2) what are the types and degrees of risk that this research presents to the subjects; (3) are the risks to the subjects reasonable in relation to the anticipated benefits, and is the research likely to result in generalizable knowledge about the subjects disorder or condition; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

To facilitate the public review and comment process, FDA has established a public docket and placed in that docket the following information relating to the proposed clinical investigation, including: Correspondence from NIH referring the proposed research protocol to HHS for consideration under 45 CFR 46.407; correspondence from FDA to NIH regarding the proposed protocol; the NIMH research protocol; the IRB deliberations on the proposed research; the parental permission documents; and the assent documents. Electronic copies of these documents 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.) These materials are also available on OHRP's website at: *http://hhs.gov/ohrp/children/*.

All written comments concerning this proposed research should be submitted to FDA's Division of Dockets Management under 21 CFR 10.20, no later than 4:30 p.m. on August 20, 2004. The background materials and 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. The background materials may also be viewed on OHRP's website at: *http://hhs.gov/ohrp/children/*.

Dated: July 29, 2004.

Lester M. Crawford,

Acting Commissioner for Food and Drugs.

Dated: July 29, 2004.

Cristina V. Beato,

Acting Assistant Secretary for Health.

[FR Doc. 04–17825 Filed 7–30–04; 3:42 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

American Indians Into Psychology Program; Correction

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on July 12, 2004. The document contained one error.

FOR FURTHER INFORMATION CONTACT: Martha Redhouse, Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, Rockville, MD 20852, Telephone (301) 443–5204. (This is not a toll-free number.)

Correction

In the **Federal Register** of July 12, 2004, in FR Doc. 04–15715, on page 41820, in the first column, Project Budget, section C should be deleted.

Dated: July 29, 2004.

Phyllis Eddy,

Acting Director, Indian Health Service.

[FR Doc. 04–17777 Filed 8–3–04; 8:45 am]

BILLING CODE 4160–16–M