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