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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@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

Dated: JUL 29 2004

July 29, 2004.

Lester M. Crawford, PhD

Lester M. Crawford,
Acting Commissioner for Food and Drugs.

JUL 29 2004

Dated: _____

July 29, 2004.

Cristina V. Beato M.D.

Cristina V. Beato,
Acting Assistant Secretary for Health.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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