



Food and Drug Administration  
Office of Pediatric Therapeutics  
Room 4B-44, HFG-2  
5600 Fishers Lane  
Rockville, MD 20857

July 23, 2004

Michael M. Gottesman, MD  
Deputy Director for Intramural Research  
National Institutes of Health  
Bethesda, MD 20892

**Subject: FDA Review under 21 CFR 50.54 of Protocol Entitled "Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study"**

**Re: Notification of Intent to Seek Public Comment**

Dear Dr. Gottesman:

As we discussed during our conversation on June 18, 2004, the Food and Drug Administration (FDA), in conjunction with the Office of Human Research Protection (OHRP) at the Department of Health and Human Services, intends to solicit public comment on the above-referenced protocol. The FDA and OHRP will then convene an advisory committee to review the protocol, in accordance with the requirements of 21 CFR § 50.54 and 45 CFR § 46.407.

FDA believes the public cannot provide meaningful comment on the proposed clinical investigation without having access to sufficiently detailed information regarding the research. Therefore, FDA intends to make publicly available all information we believe to be necessary for the public to be able to consider and comment on the proposed clinical investigation. This includes the protocol and all investigational review board (IRB) materials sent to FDA and OHRP as part of the referral for review.

This letter is to notify you of FDA's intent to make these materials available in a public docket on FDA's website, and to provide hard copies to the public upon request. If you have any objections to the public availability of these materials, please contact me as soon as possible so we can discuss the matter. Otherwise, in order to facilitate this process, we would appreciate your sending the protocol and all relevant materials, in electronic format to the FDA at the following email address: [terrie.crescenzi@oc.fda.gov](mailto:terrie.crescenzi@oc.fda.gov).

We are aware that you have received a similar letter from OHRP regarding the planned public availability of these materials. Given that the materials will be posted on FDA's website, this letter is designed to inform you of FDA's intentions in this matter.

Thank you for your assistance and we look forward to working with you on this process.

Sincerely,

Terrie L. Crescenzi, RPh  
Policy Analyst  
Office of Pediatric Therapeutics  
Office of the Commissioner

cc: Dr. Donald Rosenstein, NIMH, NIH  
Dr. Judith Rapoport, NIMH, NIH  
Dr. Russell Katz, CDER, FDA  
Dr. Joann Less, CDRH, FDA  
Donna Katz, Esq., OGC, FDA