DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-435-0062
FAX: 301-402-2071

October 20, 2003

J. Dennis O'Connor
Vice President for Research and
Dean of the Graduate School
University of Maryland
2133 Lee Building
College Park, MD 20742-5121

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1362
Research Project: Treatment of Childhood Social Phobia
Principal Investigators: Deborah C. Beidel and Samuel M. Turner
Grant Number: 2RO1MH053703-05A2

Dear Dr. O'Connor:

The Office for Human Research Protections (OHRP) has reviewed the University of Maryland's (UM's) July 30 and September 28, 2003 reports responding to OHRP's July 1, 2003 letter requiring corrective action for findings of noncompliance with Department of Health and Human Services (HHS) regulations protecting human research subjects involving the above-referenced study.

Based upon its review, OHRP finds that the corrective actions described below adequately address OHRP's July 1, 2003 findings:

> In its July 1, 2003 letter, OHRP found that the IRB-approved consent document for the above study (a) did not include the anticipated duration of diagnostic assessments to be conducted before treatment and at three interval periods after treatment, (b) confounded the concepts of treatment and experimental intervention in a manner that was potentially misleading, and (c) did not describe the EKG procedure (and any expenses associated with the procedure) that was a requisite part of the study, as required by HHS regulations at 45 CFR 46.116(a) .
>
> **Corrective Action**: At its August 7, 2003 meeting, the UM IRB approved revisions to the informed consent document for the above research which (a) included the anticipated duration of diagnostic assessments to be conducted before treatment and at three interval periods after treatment, and (b) clarified that subjects are randomized to one of three

separate and independent study arms: (i) social effectiveness therapy, (ii) fluoxetine, or (iii) placebo. In addition, the UM IRB approved a procedure for obtaining renewed consent from all currently enrolled study subjects, including those in the preliminary assessment, intervention, and follow-up phases of the study.

On August 15, 2003, the principal investigators submitted to the UM IRB a revised informed consent form subsequently approved by the IRB which, in addition to the changes required by the IRB at its August 7, 2003 meeting, included a description of the required EKG procedure and the physiological variables that it measures.

OHRP finds that the above corrective actions are adequate and appropriate under UM's MPA. As a result, there should be no need for further OHRP involvement.

OHRP appreciates your continued commitment to the protection of human research subjects.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Dr. Timothy J Ng, Associate VP Research
P. Moser-Veillon, IRB Co-Chair
M. Rogers, IRB Co-Chair
Dr. Bernard Schwetz, OHRP
Ms. Melinda Hill, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Shirley Hicks, OHRP
Dr. Melody H. Lin, OHRP
Dr. Harold Blatt, OHRP
Commissioner, FDA
Dr. David Lepay, FDA