DEPARTMENT OF HEALTH & HUMAN SERVICES

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August 17, 2001

Fawwaz T. Ulaby, Ph.D.
Vice President for Research
University of Michigan
4080 Fleming Building
503 Thompson Street
Ann Arbor, Michigan 48109-1340

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1184

Research Project:	**Depression, Peptides and Steroids in Cushing's Syndrome**
Protocol Number:	**IRB MED 87-155**
Investigators:	**Dr. Monica N. Starkman, Dr. David E. Schteingart, Dr. Stanley Berent, Dr. J.E. Shipley, Dr. O.G. Cameron, Dr. Ziad Kronfol, Dr. Stephen Gebarski, Dr. Alan Douglass, Dr. Bruno Giordani**

Dear Dr. Ulaby:

The Office for Human Research Protections (OHRP) has reviewed your report of July 27, 2001, regarding the above referenced research. OHRP acknowledges the following corrective action taken by the University of Michigan (UM):

(1) UM has terminated protocol IRBMED 87-155 and reviewed a new protocol which does not make use of radiolabelled cortisol (IRBMED 2001-2071).

(2) The UM IRB has required that all subjects enrolled in IRBMED 87-155 who will continue with research interventions be entered into protocol IRBMED 2000-2071.

(3) UM has implemented new procedures for the identification and tracking of research subjects in the General Clinical Research Center (GCRC).

(4) UM has advertised for a Director for Regulatory Affairs within the GCRC.

(5) UM has added three new IRBs and has increased the administrative capacity of the IRB office.

(6) UM has required that investigators re-submit the initial application for protocol IRBMED 2000-575. The UM IRB has reviewed and approved the protocol with a new protocol number (IRBMED 2001-264).

(7) UM has plans to upgrade the information systems used to store and access IRB and other research related records.

OHRP finds that the corrective action described above, as well as those described in UM's April 10, 2001 report, adequately address the issues raised in OHRP's December 15, 2000 and June 11, 2001 letters to UM. As a result, there should be no need for further involvement of OHRP in this matter.

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

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Judith A. Nowack, U. Michigan
Dr. David C. Smith, U. Michigan, IRB MED Chair
Dr. Charles J. Kowalski, U. Michigan, IRB HLTH Chair
Dr. Eugene Burnstein, U. Michigan, IRB BEHAVSCI Chair
Dr. Gerald T. Gardner, U. Michigan, IRB DRBN Chair
Dr. Suzanne M. Selig, U. Michigan, IRB FLINT Chair
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Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Raymond Farkas, FDA
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Mr. Barry Bowman, OHRP