DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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November 27, 2000

Mark R. Neaman
President and Chief Executive Officer
Evanston Northwestern Healthcare Corporation
1301 Central Street
Evanston, Illinois 60201

Leopold Selker, Ph.D.
Senior Vice President for Research
Chief Administrative Officer
Evanston Northwestern Healthcare Research Institute
2650 Ridge Avenue
Evanston, Illinois 60201

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1396

Research Activities Conducted by the Clinical Pharmacology Unit

Dear Mr. Neaman and Dr. Selker:

The Office for Human Research Protections (OHRP) has reviewed your letter dated 7 November 2000, regarding the above referenced research activities.

OHRP finds that Evanston Northwestern Healthcare Corporation (ENH), in accordance with the required action stipulated by OHRP in its October 11, 2000 letter, has developed a satisfactory corrective action plan to ensure that the ENH Institutional Review Board (IRB) reviews and approves all proposed changes in research protocols, during the period for which IRB approval has already been given, prior to initiation of such changes.

Furthermore, OHRP has determined that ENH has adequately addressed the additional concerns that were raised by OHRP's October 11, 2000 letter. In particular, OHRP acknowledges the following:

(1) The ENH IRB has directed a change in the payment schedule for subjects participating in research studies conducted by the ENH Clinical Pharmacology Unit so that payment is made under a prorated schedule for subjects who voluntarily withdraw prior to completion of the planned research studies.

(2) ENH conducted an appropriate investigation into the allegations regarding Dr. Antoni A. Piergies.

(3) ENH has revised its written IRB policies and procedures in response to the guidance provided by OHRP.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Mr. Robert Stanton, Director of Research, ENH
Dr. Bernard Adelson, Chair, IRB, ENH
Dr. Antoni A. Piergies, Director of Clinical Pharmacology Unit, ENH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Gregory Koski, OHRP
Dr. Melody H. Lin, OHRP
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Mr. Barry Bowman, OHRP