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

November 5, 2003

Raymond Menard, Ph.D.
Vice President, Administration
Center for Molecular Medicine and Immunology
520 Belleville Avenue
Belleville, New Jersey 07109-0023

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 00000800 (Center for Molecular Medicine and Immunology)

Dear Dr. Menard:

The Office for Human Research Protections (OHRP) has reviewed your August 12 and October 20, 2003 reports responding to OHRP's findings and concerns based upon its on-site evaluation of the Center for Molecular Medicine and Immunology (CMMI)/Garden State Cancer Center (GSCC) human subject protection program on July 22-24, 2003. GSCC's August 12, 2003 report states that GSCC dissolved its institutional review board (IRB) and suspended all studies approved by the GSCC IRB that were active and/or open to enrollment on July 24, 2003, including clinical trials and studies involving collection of tissues. GSCC's October 20, 2003 report states that GSCC entered into an IRB Authorization Agreement with an independent IRB for the limited purpose of reviewing a single protocol, "Phase 1 Trial of Radioimmunotherapy of Relapsed or Refractory Non-Hodgkin's Lymphoma With Y-Labeled Humanized LL2 IgG Antibody" (August 1, 2002) (version 5) . GSCC updated the CMMI FWA to reflect the change in its designated IRB. On September 18, 2003, the independent IRB approved the enrollment of a single subject in the protocol.

OHRP finds the above corrective actions adequate under CMMI's FWA. At this time, there should be no need for further OHRP involvement in this matter. However, OHRP must be notified if new information is identified which might alter this determination, including, but not limited to, any unanticipated problems involving risks to subjects or others [see 45 CFR 46 part 103(a) and (b)(5)], or any information indicating that risks to subjects have not been minimized [see 45 CFR 46.111(a)(2)].

OHRP appreciates GSCC's continued commitment to the protection of human research subjects. Feel free to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Office for Human Research Protections

cc: Alan Sugar, IRB Chair, NEIRB
Erin Thacker, Administrator, NEIRB
Dr. Bernard Schwetz, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Janice Walden, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Carol Weil, OHRP
Mr. Bob Meyer, OHRP
Ms. Shirley Hicks, OHRP
Ms. Melinda Hill, OHRP
Commissioner, FDA
Dr. David Lepay, FDA
Ms. Joan Mauer, NIH