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September 21, 2001

Jon E. Hart
Director, Sponsored Programs Administration
The Rockefeller University
1230 York Avenue
New York, NY 10021-6399

David D. Ho, M.D. Scientific Director Aaron Diamond AIDS Research Center 455 First Avenue New York, NY 10016

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1297

Research Project: AIDS Vaccine Trail to be Conducted in Rural China Principal Investigator: David Ho, M.D.

Dear Ms. Hart and Dr. Ho:

The Office for Human Research Protections (OHRP) has reviewed your report dated September 10, 2001 regarding the above referenced allegations. OHRP acknowledges that AIDS vaccine trials in China are in the early planning phases, that a protocol does not yet exist for such studies, and that the Principal Investigator has no research activities ongoing in China at this time.

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.

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Rockefeller University- Jon E. Hart
Aaron Diamond AIDS Research Center- David D. Ho, M.D.
September X, 2001

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,

Kristina C. Borror, Ph.D. Compliance Oversight Coordinator Division of Compliance Oversight

cc: Dr. Shigeru Sassa, Rockefeller

Mr. Sidney Ho, Aaron Diamond

Dr. Vincent A. Fischetti, IRB Chair, Rockefeller & Aaron Diamond

Commissioner, FDA

Dr. David Lepay, FDA

Dr. James F. McCormack, FDA

Dr. Greg Koski, OHRP

Dr. Melody H. Lin, OHRP

Dr. Michael A. Carome, OHRP

Dr. Jeffrey M. Cohen, OHRP

Mr. George Gasparis, OHRP

Ms. Freda Yoder, OHRP