



FOR US POSTAL SERVICE DELIVERY:

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January 22, 2001

Chi Van Dang, M.D., Ph.D.
Vice Dean for Research
The Johns Hopkins University
School of Medicine
School of Medicine Administration Building, Room 124
720 Rutland Avenue
Baltimore, MD 21205-2196

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1011

Research Project: A Randomized Double Blind Comparative Trial of Ambisome (Liposomal Amphotericin B) Versus Amphotericin B in the Empiric Treatment of Febrile Neutropenic Patients

Project Numbers: RPN 95-03-03-03

Dr. Dang:

The Office for Human Research Protection (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed Dr. Elias Zerhouni's August 16, 1999 report regarding the above referenced research project that was submitted in response to OPRR's July 12, 1999 letter. OHRP apologizes for the delay in its response to Dr. Zerhouni's report.

Based upon its review of Dr. Zerhouni's report, OHRP makes the following determinations:

- (1) OHRP finds that parental permission was obtained and documented for the complainant's grandson for his participation in the above referenced research project in accordance with the requirements of Department of Health and Human Services regulations at 45 CFR 46.116, 46.117, and 46.408.
- (2) OHRP acknowledges that (i) the above reference clinical trial did not include a placebo arm; and (ii) the complainant's grandson was assigned to the study group that received Amphotericin B.

January 22, 2001

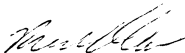
As a result, there should be no need for further involvement of OHRP in this matter. Of course OHRP must be notified should new information be identified which might alter this determination.

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

Sincerely,



Inese Z. Beitins, M.D., F.R.C.P.(C).
Compliance Oversight Coordinator
Division of Compliance Oversight



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

cc: Mr. Ronald R. Peterson, President, The Johns Hopkins Hospital
Dr. Sue K. Donaldson, Dean, School of Nursing, JHU
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