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
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April 29, 2005

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
National Institutes of Health
Building 1, Room 114
1 Center Drive
Bethesda, MD 20892

Re: Human Research Subject Protections Under Federalwide Assurance FWA-5897

Research Project:	**A Phase I Study of an Oral Histone Deacetylase Inhibitor, MS-275, in Refractory Solid Tumors and Lymphomas**
NIH Project Number:	**01-C-0124**
Intramural Institute:	**National Cancer Institute (NCI)**
Principal Investigator:	**Edward Sausville, M.D.**
Research Project:	**A Phase I Study of an Oral Perifosine with Different Loading Schedules in Patients with Refractory Neoplasms**
NIH Project Number:	**99-C-0043**
Intramural Institute:	**National Cancer Institute (NCI)**
Principal Investigator:	**Edward Sausville, M.D.**
Research Project:	**Amifostine as a Rectal Protector During Beam Radiotherapy for Prostate Cancer: A Phase II Study**
NIH Project Number:	**02-C-0215**
Intramural Institute:	**National Cancer Institute (NCI)**
Principal Investigator:	**C. Norman Coleman, M.D.**
Research Project:	**A Phase II Study of MR-Guided High Dose Rate Brachy-therapy Before and After External Beam Radiotherapy in Patients with Prostate Cancer**
NIH Project Number:	**02-C-0207**
Intramural Institute:	**National Cancer Institute (NCI)**
Principal Investigator:	**Kevin A. Camphausen, M.D.**

Research Project:	**A Pilot Study of Pirfenidone for the Treatment of Radiation-Induced Fibrosis**
NIH Project Number:	**01-C-0143**
Intramural Institute:	**National Cancer Institute (NCI)**
Principal Investigator:	**Rosemary Altemus, M.D.**

Research Project:	**Genetic Characterization of Movement Disorders**
NIH Project Number:	**2003-081**
Intramural Institute:	**National Institute on Aging (NIA)**
Principal Investigator:	**John Hardy, Ph.D.**

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed the National Institutes of Health's (NIH) May 14, 2004 and April 11, 2005 reports evaluating allegations of noncompliance with Department of Health and Human Services regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based upon its review, OHRP finds that the corrective action summarized below adequately addresses the determinations and requests set forth in OHRP's March 30, 2005 letter to NIH.

> **Corrective Action:** NIA instituted protocol tracking procedures for all new subjects, which include a requisite screening/eligibility checklist for every subject; a central protocol registry in the NIA protocol office; and the use of data entry forms. The screening/eligibility checklist is completed by the investigator evaluating each study subject. Protocol inclusion/exclusion criteria are assessed, any reasons for exclusion from the study are noted, and the outcome (i.e., inclusion or exclusion) is noted. The investigator must sign and date the checklist.

As a result, there should be no need for further OHRP involvement in this matter. OHRP appreciates NIH's continued commitment to the protection of human research subjects.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Elias Zerhouni, Director, NIH
Dr. Richard Hodes, Director, NIA
Dr. Andrew von Eschenbach, Director, NCI

Dr. Alan L. Sandler, OHSR, NIH
Ms. Joan Mauer, CTEP, NCI
Dr. Edward Sausville, NCI
Dr. C. Norman Coleman, NCI
Dr. Kevin A. Camphausen, NCI
Dr. Rosemary Altemus, NCI
Dr. John Hardy, NIA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Shirley Hicks, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Janet Fant, OHRP