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: 240 453-8218
FAX: 240 453-8297
E-mail: carol..weil@hhs.gov

February 25, 2009

James Mulshine, M.D.
Associate Vice Provost for Research
Rush University Medical Center
1735 W. Harrison, Suite 206
Chicago, IL 60612

RE: Human Research Protections Under Federalwide Assurance FWA-482 and FWA-1802

Research Project: A Phase II Trial of Doxorubicin & Docetaxel in the Neoadjuvant Treatment of Locally Advanced Breast Cancer with Correlation of Clinical, Molecular and Biological Prognostic Factors
Principal Investigators: Elizabeth Marcus, M.D. and Shalina Gupta-Burt, M.D.

Dear Dr. Mulshine:

Thank you for your February 19, 2009 report responding to our request for corrective action. On August 21, 2008, we issued determinations to Rush University Medical Center (Rush) regarding Rush institutional review board (IRB) policies and procedures. We found that Rush lacked the following written procedures required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4) and (b)(5):

(a) Procedures which the IRB will follow for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, as required by HHS regulations at 45 CFR 46.103(b)(4); and

(b) Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and any Department or Agency head [Federal Sponsor] of (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval, as required by HHS regulations at 45 CFR 46.103(b)(5).

Corrective Actions: We acknowledge that Rush has developed written procedures to address these requirements. We have determined that these corrective actions adequately address the above findings. At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate the continued commitment of your institution to the protection of human research subjects.

Sincerely,

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

cc:

Ms. Mary Jane Welch, Director, Human Subjects Protection, Rush University Medical Center
Dr. Allen C. Korenblit, IRB Chair, Rush University Medical Center, IRB #1
Dr. Howard M. Kravitz, IRB Chair, Rush University Medical Center, IRB #1
Commissioner, FDA
Dr. Joanne Less, FDA