DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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December 7, 2006

Michael Dunn, M.D.
Dean and Executive Vice President
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226-0509

RE: Human Research Subject Protections Under Federalwide Assurance FWA 820

Research Project:	**A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of Etoricoxib in Patients with Osteoarthritis or Rheumatoid Arthritis**
Protocol Number:	**02-224**
Principal Investigator:	**Mary Ellen Csuka, M.D.**

Dear Dr. Dunn:

The Office for Human Research Protections (OHRP) has reviewed the Medical College of Wisconsin's (MCW) January 30, 2006 report in response to OHRP's December 21, 2005 letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving the above-referenced research.

Based on our review of your report, OHRP notes the following:

(1) The MCW report states:

> (a) "Our internal investigation of this allegation revealed that, due to an inadvertent administrative oversight, the IRB's [institutional review board] termination of its approval for the Study was reported only to the U.S. Department of Health and Human Services, Food and Drug Administration

('FDA') and the Study's sponsor, Merck & Co., Inc."

(b) "MCW's failure to *also* report this termination to OHRP was not consistent with the IRB policies and procedures in place at the time or with those in effect now." [Emphasis in original]

(2) OHRP finds that the MCW failed to report the termination of the above-referenced research, as required by HHS regulations at 45 CFR 46.103(a) and (b)(5).

Corrective Actions: The MCW IRB written procedures were updated to include OHRP's most recent guidance on reporting of IRB suspensions and terminations. In addition, MCW has had a recent audit of its IRB activities by an independent consultant. As a result of this audit, the MCW will be providing additional funds to its IRB to hire new staff, provide enhanced training to IRB staff and members, and revise and update its existing IRB procedures.

OHRP finds that the corrective actions noted above adequately address the above finding and are appropriate under the MCW FWA.

As a result of the above determination, 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 these determinations

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. David Gutterman, Senior Associate Dean for Research, MCW
Dr. Lance Weinhardt, IRB Chair, MCW
Dr. Mary Ellen Csuka, MCW
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
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Ms. Patricia El-Hinnawy, OHRP

Ms Carla Brown, OHRP