DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for HumanResearch Protections
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January 23, 2003

B. Lyn Behrens, M.B., B.S.
President
Loma Linda University
Loma Linda, CA 92350

Barry L. Taylor, Ph.D.
Vice President for Research Affairs
Loma Linda University
Loma Linda, CA 92350

Zareh Sarrafian, M.B.A.
Chief Executive Officer
Loma Linda University Behavioral Medicine Center
1710 Barton Road
Redlands, CA 92373

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1295

Research Project: Double-Blind, Randomized, Placebo-Controlled Long-Term Low Dose Perchlorate Exposure Study

Protocol Number: 799735

Principal Investigator: Anthony Firek, M.D.

Dear Mr. Behrens, Dr. Taylor and Mr. Sarrafian:

The Office for Human Research Protections (OHRP) has reviewed the Loma Linda University's (LLU) report dated January 10, 2003. OHRP has determined that the corrective actions summarized below appropriately address the findings presented in OHRP's letter of November 14, 2002 and are appropriate under the LLU MPA.

(1) The LLU Institutional Review Board (IRB) has approved a revision to the informed consent document to include an accurate description of how the maximum level of perchlorate exposure during the study would compare to maximum level of perchlorate exposure expected from drinking perchlorate-contaminated drinking water. The LLU IRB has required that the revised informed consent document be presented to currently enrolled subjects to obtain signed confirmation of the subjects' willingness to continue participation in the above-referenced research. The LLU IRB has also required that former subjects of the above-referenced research be informed by written correspondence of the informed consent revision regarding perchlorate exposure.

(2) LLU has advised the principal investigator of errors in documents presented to the LLU IRB regarding the level of perchlorate to which subjects were to be exposed in the above-referenced research relative to the maximum level of exposure expected from drinking perchlorate-contaminated drinking water. LLU has also advised the LLU IRB that substantive discrepancies found in documentation submitted for proposed research must be documented and resolved with the principal investigator.

(3) LLU has required that any future proposed research similar to the above-referenced research be considered by the LLU IRB for classification as a toxicology study.

(4) LLU has advised the LLU IRB that protocol amendments to add a new exposure group and to increase the number of subjects are to be considered for approval by the IRB at a convened meeting.

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 this determination.

OHRP appreciates the commitment of LLU to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Robert J. Meyer
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Richard H. Hart, Chancellor & CEO, LLU
Dr. G. William Saukel, Chair, LLU IRB
Commissioner, FDA
Dr. David A. Lepay, FDA
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