

October 19, 2001

TO: Ashok Agarwal, Ph.D. / A19.1

Office of the Institutional
Review Board / Wb2
Office: 216/444-2924
Fax: 216/445-4094
E-mail: IRB_APP@ccf.org

RE: IRB 4562: Levocarnitine Fumarate and Acetyl-L-Carnitine(ProXeed) combined Supplementation in Subfertile Males with High Reactive Oxygen Species (Sigma-Tau HealthScience, Inc.)

Dear Dr. Agarwal:


Thank you for your response dated October 11, 2001 to requests from a prior review of your application for the new study listed above has been reviewed and approved through the expedited review process on October 17, 2001. This type of response qualifies for expedited review under FDA and OHRP regulations. The Institutional Review Board will be notified of this activity.

This is to confirm that your application including the Clinical Study Protocol STHS dated 01-01, the Letter from Biostatistics and Epidemiology dated April 25, 2001, the Addendum 1 Agreement for Clinical Investigation was approved. The consent form dated Revised January, 2001 as most recently revised is approved for the period of 10/17/01 to 08/30/02. You must obtain signed written consent from all subjects. Attached is a copy of the IRB approved and stamped informed consent document. This study involves at least one investigational new drug.

The study is subject to continuing review on or before August 30, 2002. Recruitment and new enrollment beyond the expiration date is prohibited by federal regulations.

Any changes to the study, unanticipated problems, or serious adverse events or unanticipated adverse events must be promptly reported and approved by the IRB. You must submit a continuation/progress report prior to the expiration date for review and approval by the IRB.

Sincerely,


Daniel Beyer, MS, MHA
IRB Executive Director

DB:sr Attachment (Informed Consent Document)