NDA 20-182/S-006

Sigma-Tau Pharmaceuticals Inc.
Attention: A.C. Hanzas
Director, Regulatory Affairs
800 S. Frederick Ave., Suite 300
Gaithersburg, MD 20877

Dear Mr. Hanzas:

Please refer to your supplemental new drug application dated, January 29, 1999, received February 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Carnitor (levocarnitine) Injection, 200mg/mL (in 2.5 mL and 5 mL ampoules).

We acknowledge receipt of your submissions dated May 6, June 10 and 23, August 27, October 8 (from counsel) and 14, November 5 and 15, and December 1, 3 and 13, 1999.

This supplemental new drug application provides for the use of Carnitor injection for the prevention and treatment of carnitine deficiency in patients with end stage renal disease who are undergoing dialysis.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted December 13, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Under 21 CFR 314.55(d) you are not required to complete a pediatric assessment for this application because an orphan designation has been granted under 21 CFR Part 316, Subpart C for this indication.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-182/S-006." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Maureen Hess, MPH, RD, Regulatory Health Project Manager, at (301) 827-6411.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug
Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research