DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-948/S-024
NDA 19-257/S-011

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

Dear Mr. Hanzas:

Please refer to your supplemental new drug applications:

NDA	Supplement	Drug Product	Submitted	Received
18-948	S-024	Carnitor (levocarnitine) Tablets	March 20, 2007	March 21, 2007
19-257	S-011	Carnitor (levocarnitine) Oral Solution	June 28, 2006	June 29, 2006

We acknowledge receipt of your submissions dated August 24 and October 19, 2006, and January 17, 2007 for NDA 19-257.

Supplement S-011 (NDA 19-257) provides for a sugar-free formulation of Carnitor Oral Solution, called Carnitor SF (levocarnitine) Sugar-Free Oral Solution, 1 gram per 10 mL, as well as minor revisions to the package insert (PI).

Supplement S-024 (NDA 18-948) provides for the addition of the sugar-free product to the combined package insert for the tablets and oral solution.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), and immediate container and carton labels submitted June 28, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 18-948/S-024 and NDA 19-257/S-011**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolism and Endocrinology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

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