DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 15 1999

TRANSMITTED VIA FACSIMILE

A.C. Hanzas
Director, Regulatory Affairs
sigma-tau Pharmaceuticals, Inc.
Regulatory Department
800 S. Frederick Ave.
Suite 300
Gaithersburg, MD 20877

RE: NDA 18-948
Carnitor (levocarnitine)
MACMIS #8090

Dear Mr. Hanzas:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional material for Carnitor (levocarnitine) that is lacking in fair balance or otherwise misleading. Reference is made to a journal advertisement (TPN-5(BPY-6)), submitted under cover of Form FDA 2253 on May 20, 1999. The publication of this material by sigma-tau Pharmaceuticals, Inc. (sigma-tau) violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. DDMAC requests that the use of the above referenced material and those containing the same or similar violations cease immediately.

Lack of Fair Balance

Promotional materials may be lacking in fair balance, or otherwise misleading if they fail to present information relating to side effects and contraindications, with a prominence and readability reasonably comparable to the presentation of efficacy information. The aforementioned journal advertisement makes several effectiveness claims in the body of the ad, yet fails to provide any risk information.

A.C. Hanzas
Director, Regulatory Affairs
sigma-tau Pharmaceuticals, Inc.

Inadequate Brief Summary

Advertisements for prescription drugs shall present a true statement of information in brief summary relating to side effects, contraindications, and effectiveness. This journal ad primarily contains claims about the intravenous formulation, however the brief summary presented is for the tablets, oral solution, and intravenous formulations. This combined brief summary containing such contradictory information as, "Not for parenteral use" from the tablet and oral solution package insert is misleading and confusing to the reader.

Sigma-tau should immediately cease using the journal ad, and all other promotional materials for Carnitor that contain the same or similar violations. Sigma-tau should submit a written response to DDMAC, on or before July 29, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, sigma-tau should include a list of all promotional materials that were discontinued, and the discontinuation date.

Sigma-tau should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds sigma-tau that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS #8090 and NDA 18-948.

Sincerely,

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications