DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-785/S035

Sigma-tau Pharmaceuticals, Inc.
800 South Frederick Ave.
Gaithersburg, MD 20877

Attention: A.C. Hanzas
Director, Regulatory Affairs

Dear Mr. Hanzas:

Please refer to your supplemental new drug application dated July 3, 2002, received July 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Matulane (procarbazine HCl) Capsules.

This "Changes Being Effected" supplemental new drug application provides for a revision in the labeling to add statements in the Warnings, Information for Patients, and Adverse Reactions sections regarding the risk of secondary lung cancer in patients with Hodgkin's disease who are treated with procarbazine in combination with other chemotherapy and/or radiation and the effects of tobacco on this risk.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 3, 2002.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 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, call Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

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

/s/

Richard Pazdur

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