DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN -6 1997

Sam Boddapati, Ph.D.
Director, Regulatory Affairs
SuperGen, Inc.
3158 Des Plaines Avenue, Suite 10
Des Plaines, IL 60018

RE: NDA# 20-122
Nipent Injection (pentostatin for injection)
MACMIS ID #5010

Dear Dr. Boddapati :

Reference is made to SuperGen Inc's (SuperGen) submission of a convention panel (800Cl) submitted under cover of FDA Form 2253. The Division of Drug Marketing, Advertising and Communications (DDMAC) finds this advertisement to be in violation of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder.

Specifically, the panel is misleading because it is lacking in fair balance with respect to both content and presentation. Promotional materials should present true information relating to side effects and contraindications that is comparable in scope, depth and detail with the claims for effectiveness or safety. This panel presents many prominent and specific claims of effectiveness. However, the only risk information presented consists of three statements in small font that state: "*Most patients treated for hairy cell leukemia in the pivotal studies experienced an adverse event. The drug association of some adverse events is uncertain as they may be associated with the disease itself. Most adverse events that were assessed for severity were either mild or moderate and diminished in frequency with continued therapy.*" The approved product labeling for Nipent is replete with important warnings, precautions and severe adverse reactions associated with the use of the product, including, but not limited to:

- boxed warning regarding acute and/or fatal pulmonary toxicity in patients receiving certain concomitant chemotherapeutic agents
- dose-limiting severe renal, liver, pulmonary, and CNS toxicities with higher doses than recommended
- myelosuppression
- severe rashes requiring treatment delays
- elevated liver enzymes

Therefore, to present a fair balance between risks and benefits of the drug, the most important of these warnings, precautions and adverse reactions should be included in promotional materials for Nipent.

Promotional materials should present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug. This panel presents efficacy claims with far more prominence than that of risks associated with Nipent, and is therefore lacking in fair balance.

SuperGen should immediately discontinue use of this and other promotional materials that are similarly violative. Please respond in writing by January 15, 1997, with your intent to comply with the above. Address your response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-240, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds SuperGen that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5010 in addition to the NDA number.

Sincerely,

Tracy L. Acker, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications