DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-763

SuperGen, Inc.
Attention: Sam Boddapati, Ph.D.
Senior Director, Regulatory Affairs
4140 Dublin Boulevard, Suite 200
Dublin, CA 94568

Dear Dr. Boddapati:

Please refer to your new drug application (NDA) dated May 13, 2002, received May 14, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Mytozytrex™ (mitomycin for injection), 5 mg.

We acknowledge receipt of your submission(s) dated March 20, May 21, June 12, June 13, September 11, September 12, September 27, October 4, October 10, October 21, October 24, November 4, November 5, November 6(2), November 7, November 12, November 13, and November 14, 2002. The May 13, 2002 submission constituted a complete response to our December 11, 1998 action letter.

This application provides for Mytozytrex™ (mitomycin for injection), 5 mg use as follows:

> Mitozytrex is not recommended as single-agent, primary therapy. Mitomycin has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Mitozytrex is not recommended to replace appropriate surgery and/or radiotherapy.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and immediate container and carton labels). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 50-763**." Approval of this submission 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 this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

Sincerely,

{See appended electronic signature page}

Grant Williams, M.D.
Deputy Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Labeling, immediate container and carton labels – 14 pages

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

/s/

Grant Williams

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