DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-237 S-008 & S-009

MGI PHARMA, Inc.
Attention: Jo H. Gustafson, Ph.D.
5775 West Old Shakopee Road
Suite 100
Bloomington, Minnesota 55437-3107

Dear Dr. Gustafson:

We acknowledge your supplemental new drug applications, S-008 dated July 19, 1996, received July 22, 1996, and S-009 dated October 07, 1996 and received October 08, 1996 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Salagen® (pilocarpine HCI) Tablets.

We acknowledge receipt of your submissions for S-008 dated: September 29, 1997; February 6 and March 5, 1998; July 7 and September 14, 1999; March 20, 2000; and February 15, 2002. We acknowledge receipt of your submissions for S-009: February 22, August 12, September 15, October 13, November 12 and 30, December 23, 1999; June 23, and November 6, 2000; and February 15, 2002.

These supplemental applications provide for the clarification of the metabolic fate of Salagen in subsets of patients with renal or hepatic insufficiency (008) and the addition of post approval carcinogenicity data (009).

We have completed the review of these supplemental applications, including the submitted final labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed approved labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed approved labeling text.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 10 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "Final Printed Labeling" for approved supplemental NDA 20-237/S-008 and S-009. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the label may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, MD 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, 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 20852-9787

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, please contact Kalyani Bhatt, Project Manager, at (301) 827-2020.

Sincerely yours,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
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/

Markham Luke
6/10/02 09:09:18 AM
Acting for Dr. Jonathan Wilkin