

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20237/S-007

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	Included	Pending Completion	Not Prepared	Not Required
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EA/FONSI			X	
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Correspondence	X			

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Approval Package for:

Application Number: NDA 20-237/S-007

Trade Name: SALAGEN TABLETS

Generic Name:(pilocarpine HCL)

Sponsor: MGI Pharma, Inc.

Approval Date: February 11, 1998

Indication: Provides for the treatment of symptoms of dry mouth in patients with Sjogren's syndrome.

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Application Number: NDA 20-237/S-007

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 20-237/S-007

Food and Drug Administration
Rockville MD 20857

MGI PHARMA, Inc.
Attention: Jo H. Gustafson, Ph.D.
Suite 300E, Opus Center
9900 Bren Road East
Minnetonka, MN 55343

FEB 11 1998

Dear Dr. Gustafson:

We acknowledge your supplemental new drug application dated February 11, 1997, received February 12, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Salagen® (pilocarpine HCl) Tablets.

We acknowledge receipt of your submissions dated February 19, March 27, April 8 (2), and 25, May 8 (2), June 2, 4, 9, and 17, July 31, August 14, October 8, 29, and 30, November 14 and 21, December 11, 19, and 22, 1997; and January 14, 19, 22, 26, and 30, and February 2 and 10, 1998. The User Fee goal date for this application is February 12, 1998.

The supplemental application provides for the treatment of symptoms of dry mouth in patients with Sjogren's syndrome.

We have completed the review of this supplemental application, including the submitted draft 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 enclosed approved labeling text. Accordingly, the supplemental application is 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 ten 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-007. 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 that labeling 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:

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

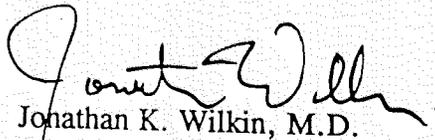
Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

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 Roy Blay, Ph.D., 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