DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 24 1997

TRANSMITTED VIA FACSIMILE

Jo H. Gustafson, Ph.D.
Director, Regulatory Affairs
MGI Pharma, Inc.
Suite 300E, Opus Center
9900 Bren Road East
Minneapolis, Minnesota 55343-9667

RE: NDA 20-237
Salagen (pilocarpine hydrochloride) 5mg Tablets
MACMIS File ID# 5830

Dear Dr. Gustafson:

This letter is in reference to MGI Pharma, Inc.'s (MGI) submission, dated September 15, 1997, of promotional materials under cover of Form FDA 2253 for Salagen Tablets. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed MGI's submission of a formulary letter identified as 50-8080 and considers the promotional material to be false and/or misleading in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Fair Balance

> The formulary letter fails to present any information relating to side effects and contraindications or other balancing risk information related to the use of Salagen. In the letter, MGI claims that "Salagen is the only therapy proven effective for radiation-induced dry mouth" and that Salagen "is the only product listed on the National Formulary that has been shown to help head and neck cancer patients with this condition." MGI presented claims for Salagen, but did not include balancing risk information associated with the use of the drug.

DDMAC requests that MGI add balancing risk information to all future copies of this promotional letter and to any similar promotional materials that make product benefit claims but lack fair balance. This balancing risk information should be presented in a manner comparable in prominence and readability as the presentation of information relating to the effectiveness of the drug.

MGI should immediately discontinue the use of this promotional letter and any other promotional materials that are false and/or misleading and lack fair balance. We request that MGI respond to DDMAC by October 8, 1997, regarding this issue.

If you have any questions, please contact me by telephone at (301) 827-2831, by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds MGI that only written communications are considered official.

In all future correspondence regarding this matter, please refer to the MACMIS File ID# 5830, in addition to the NDA number.

Sincerely,

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications