DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 13 1998

TRANSMITTED VIA FACSIMILE

Brenda Horn
Regulatory Affairs
Galderma Laboratories, Inc.
3000 Alta Mesa Boulevard
Suite 300
Fort Worth, Texas 76133

RE: **NDA 19-737**
MetroGel (metronidazole topical gel) Topical gel, 0.75%
NDA 20-531
MetroCream (metronidazole topical cream) Topical Cream, 0.75%
MACMIS ID # 6274

Dear Ms. Horn:

Reference is made to Galderma Laboratories, Inc.'s (Galderma) submissions of FDA Form-2253 for MetroGel (metronidazole topical gel) Topical gel 0.75% and for MetroCream (metronidazole topical cream) Topical Cream, 0.75%, dated January 19, 1998, and January 30, 1998. These submissions included a sales aid identified as 303-168.

As part of the Division of Drug Marketing, Advertising and Communications' (DDMAC) routine monitoring of prescription drug advertising, DDMAC has reviewed this sales aid and has determined that it is lacking in fair balance or otherwise misleading, in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, the sales aid fails to present any information relating to risks associated with the product. Promotional materials should present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug.

Accordingly, DDMAC requests that Galderma take the following actions:

1. Immediately discontinue the use of the above identified sales aid, as well as any other advertising and promotional labeling pieces that are lacking in fair balance.

2. Submit to the undersigned a written response of Galderma's intent to comply with number one, on or before February 27, 1998. DDMAC requests that this written response also include a list of promotional pieces that have been discontinued.

If Galderma has any questions or comments, please contact me by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to the MACMIS ID 6274, in addition to the NDA number.

Sincerely yours,

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications