DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAR 20 1998

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%
MACMIS ID # 6444

Dear Ms. Horn:

Reference is made to Galderma Laboratories, Inc.'s (Galderma) submission under cover of FDA Form-2253, dated February 23, 1998, of a direct-to-consumer (DTC) television broadcast advertisement video and script for MetroGel (metronidazole topical gel) Topical Gel 0.75%. As part of the Division of Drug Marketing, Advertising and Communications' (DDMAC) routine monitoring of prescription drug advertising, DDMAC has reviewed the broadcast advertisement, and has determined that it is false and/or misleading in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically:

- The broadcast advertisement is lacking in fair balance or otherwise misleading because it minimizes adverse events by presenting the required information relating to side effects or contraindications by means of a general term for a group, in place of disclosing each specific side effect and contraindication. For example, Galderma uses the phrase "skin discomfort" to group the adverse events of burning, skin irritation, dryness, and temporary redness that are listed in the product labeling. Grouping these side effects under the term "discomfort" also minimizes their significance to the consumer.

- Given that the broadcast advertisement discloses the contraindication to MetroGel, the information should be communicated in language that is understandable to the consumer. However, Galderma uses the term

"hypersensitive" in its disclosure of the contraindication. Furthermore, the phrase "should avoid" does not fully communicate to the consumer the meaning of a contraindication.

- For the broadcast advertisement, DDMAC advises Galderma that its mechanism for ensuring "adequate provision" for disseminating the approved package labeling for its product in connection with the broadcast advertisement is not adequate. The FDA issued a draft guidance on August 8, 1997, that clarified the Agency's current thinking regarding one acceptable multifaceted approach for fulfilling the requirements for the disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human drugs. The broadcast advertisement in question lacks a mechanism to provide package labeling to consumers with restricted access to sophisticated technology, such as the Internet, and those who are not active information seekers. The broadcast advertisement contains no statement that consumers can obtain additional product information in magazines, newspapers or brochures available at various publicly accessible, convenient locations like groceries or libraries.

DDMAC requests that Galderma take the following actions:

1. Immediately discontinue the use of the above identified television broadcast advertisement.

2. Submit to the undersigned a written response of Galderma's intent to comply with number one, on or before April 3, 1998.

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# 6444, in addition to the NDA number.

Sincerely,

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