NDA 20-901

Galderma Laboratories, Inc.
Attention: Christine E. Shank
Senior Director, Regulatory Submissions
3000 Alta Mesa Boulevard, Suite 300
Fort Worth, Texas 76133

Dear Ms. Shank:

Please refer to your new drug application (NDA) dated November 28, 1997, received December 2, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MetroLotion™ (metronidazole lotion) Topical Lotion, 0.75%.

We acknowledge receipt of your submissions dated January 15, February 9 and 12, March 25, April 9, May 1, June 10, July 10, August 17 and 21, September 14 and 15, October 2, and November 3, 17, 19 and 23, 1998.

This new drug application provides for the use of MetroLotion™ (metronidazole lotion) Topical Lotion, 0.75%, for treatment of inflammatory papules and pustules of rosacea.

We have completed the review of this application, as amended, 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 labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for package insert and immediate container labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 "FPL for approved NDA 20-901." Approval of this submission by FDA is not required before the labeling is used.

We remind you that any drug product lot which was the result of the, described on page 5 of the June 10, 1998 submission, should not be released for marketing prior to approval of a supplement

We understand that the pharmacokinetic study of this formulation on diseased subjects is complete, and the study report will be submitted by March, 1999.

In addition, please submit three copies of the introductory promotional materials 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 materials and the package insert directly to:

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

Please submit one market package of the drug product when it is available.

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, contact Millie Wright, Project Manager, at (301)827-2020.

Sincerely,

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