CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-743

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-743

SEP 26 1997

Dermik Laboratories, Inc.
Attention: Ronald F. Panner
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

Dear Mr. Panner:

Please refer to your new drug application dated September 30, 1996, received October 2, 1996, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Noritate® (metronidazole cream) Cream, 1%.

We acknowledge the receipt of your submissions dated October 10 and 28, November 1, 13, 14 (two) and 22, December 2, 13, 19 and 20, 1996; January 31, February 4, 5 and 14, April 9 and 14, June 11, 13 and 20, July 1, 21 and 28, August 1, 5 and 26, and September 2 and 26, 1997. The User Fee goal date for this application is October 2, 1997.

This new drug application provides for the topical treatment of inflammatory lesions and erythema of rosacea.

We have completed the review of this 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 revised draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed revised draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit twenty 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 NDA 20-743. 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.

We acknowledge your Phase 4 commitments specified in your submission dated August 26, 1997, and your facsimile dated September 26, 1997. These commitments are described below:

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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:

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

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug when its 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, please contact Olga Cintron, R.Ph., Project Manager, at (301) 827-2020.

Sincerely yours,

9/26/97

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