DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-846

APR 29 1998

Novartis Pharmaceuticals Corporation
Attention: James L. DeMartino, Ph.D.
Associate Director, Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Dr. DeMartino:

Please refer to your new drug application dated April 29, 1997, received April 29, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine) Dermgel, 1%.

We acknowledge receipt of your submissions dated May 30, June 20, August 28, Sept 3, 5, and undated (26 receipt date), October 23 and 28, and November 18, 1997, and January 23, February 25, and April 3, 28 and 29, 1998. The User Fee goal date for this application is April 29, 1998.

This new drug application provides for the topical treatment of the following dermatologic infections: tinea (pityriasis) versicolor due to *Malassezia furfur* (formerly *Pityrosporum ovale*), tinea pedis (athlete's foot) or tinea corporis (ringworm), due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*.

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 approved 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 approved labeling text. 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 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 "FINAL PRINTED LABELING" for approved NDA 20-846. 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.

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 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, please contact Susan Kummerer, M.S., Project Manager at (301) 827-2020.

Sincerely yours,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research