DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-124

Novartis Pharmaceuticals Corporation
Attention: Patricia McGovern
Associate Director, Regulatory Affairs
59 Route 10
East Hanover, NJ 07936

MAR 17 2000

Dear Ms. McGovern:

Please refer to your new drug application (NDA) dated May 14, 1999, received May 17, 1999, submitted pursuant to section 505(b)of the Federal Food, Drug, and Cosmetic Act for Lamisil® (terbinafine hydrochloride solution) Solution, 1%.

We acknowledge receipt of your submissions dated June 10, July 1 (two) and 13, August 2 and 27, October 7, 12, 21, 22 and 27, and December 17, 1999; January 17, 26 and 28 and March 6 and 17 (two), 2000.

This new drug application provides for use without prescription of Lamisil® AT™ Spray Pump (terbinafine hydrochloride solution, 1%) and Lamisil® AT™ Solution Dropper (terbinafine hydrochloride solution, 1%) for the treatment of interdigital-type tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm) due to *Trichophyton rubrum*, *Trichophyton mentagrophytes* and *Epidermophyton floccosum*.

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 agreed upon 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 the package insert, immediate container and carton labels). The enclosed, revised package insert, immediate container and carton labels were stated to be acceptable in your fascimiles dated March 17, 2000. 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 21-124." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to

contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit one copy 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. For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to approved NDA 21-124.

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, call Kevin Darryl White, Project Manager, at (301) 827-2020 or Elizabeth F. Yuan, LTJG, R.Ph., Assistant Regulatory Management Officer, at (301) 827-2222.

Sincerely,

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

Charles Ganley, M.D.
Director
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