# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number: NDA 20-749**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-749

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
Attention: Mrs. Patricia McGovern, Assistant Director
59 Route 10
East Hanover, NJ 07936-1080

OCT 17 1997

Dear Mrs. McGovern:

Please refer to your new drug application dated October 17, 1996, received October 18, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine hydrochloride solution) Solution, 1%.

We acknowledge receipt of your additional communications dated October 21 and 25, November 4, and December 17, 1996; January 9, 20 and 22, February 14, March 4 and 19, June 16 and 30, August 29, September 5, 9, 15, 16, 23 and 26, and October 7, 9, 16 (2) and 17, 1997. The User Fee goal date for this application is October 18, 1997.

This new drug application provides for the topical treatment of the following dermatologic conditions: tinea (pityriasis) versicolor due to *Malassezia furfur* (formerly *Pityrosporum ovale*), and tinea pedis (athlete's foot), tinea cruris (jock itch), 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 revised 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 labeling. The enclosed revised labeling was stated to be acceptable to you in the facsimile of your letter dated October 17, 1997. In addition, your container label and carton must be revised to show identical storage conditions to those stated in the attached revised labeling. Marketing the product with FPL that is not identical to this labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL, including the revised label and carton, as soon as they are 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 20-749. 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 remind you of your Phase 4 commitments dated October 16, 1997. These commitments, along with any completion dates agreed upon, are listed 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. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment.

The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. 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 a commitment for the following:

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 Frank H. Cross, Jr., M.A., LCDR, Regulatory Management Officer, 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

Enclosure

cc:

Original NDA 20-749
HFD-540/DIV FILE (with labeling)
HFD-002/ORM (with labeling)
HFD-105/Office Director/Weintraub
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFI-20/Press Office (with labeling)
HFD-540//DIV DIR/Wilkin (with labeling)
HFD-540/MO/Toombs (with labeling) 10/8/97
HFD-540/CHEM/Vidra (with labeling) 10/16/97
HFD-540/PHARM/Mainigi (with labeling) 10/02/97
HFD-725/BIOSTATS/Thomson (with labeling) 10/06/97
HFD-160/MICRO/Sweeney (with labeling) FHC 10/3/97 by E-mail
HFD-520/CLIN MICRO/Altaie (with labeling) 10-3-97
HFD-540/PM/Cross (with labeling) FHC

Concurrences:

HFD-540/SPM/Kozma-Fornaro (with labeling) 10/16/97
HFD-540/CHEM TL/DeCamp (with labeling) 10/16/97
HFD-540/PH/TOX TL/Jacobs (with labeling) 10/17/97
HFD-725/STAT TL/Srinivasan (with labeling) 10/09/97
HFD-880/BIOPHARM/Bashaw (with labeling 10/7/97
HFD-540/MO TL/Walker/ (with labeling)
HFD-160/MICRO TL/Cooney (with labeling) FHC 10/3/97 by E-mail
HFD-520/MICRO TL/Sheldon (with labeling) 10/7/97

Drafted by: fhc/September 9, 1997/c:\wpfiles\nda\nda20749\nda20749.ap1
Initialed by:
Final:

**APPROVAL (AP)** [with Phase 4 Commitments]