CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20-980

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CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20-980

Trade Name: Lamisil Cream 1%

Generic Name:(terbinafine hydrochloride cream)

Sponsor: Novartis Consumer Health, Inc.

Approval Date: March 9, 1999

Indication: Provides for use without prescription of Lamisil (terbinafine hydrochloride cream) Cream, 1%, for the treatment of tinea pedis (althlete's foot), tinea crurus (jock itch) and tinea corporis (ringworm) due to Epidermophyton floccosum, Trichophyton mentagrophytes and Trichophyton rubrum.

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Application Number: NDA 20-980

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-980

MAR 9 1999

Novartis Consumer Health, Inc.
Regulatory Affairs
Attention: Christine Babiuk, Ph.D., Associate Director
560 Morris Avenue
Summit, NJ 07901-1312

Dear Dr. Babiuk:

Please refer to your new drug application dated March 27, 1998, received March 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine hydrochloride cream) Cream, 1%.

We acknowledge receipt of your communications dated May 19 and 27, June 15 and 24, September 3, October 15 and 27 (2), November 24, December 17, 1998; January 28, February 16 and 24, March 3 (2) and 5, 1999.

The user fee goal date for this application is March 30, 1999.

This new drug application provides for use without prescription of Lamisil (terbinafine hydrochloride cream) Cream, 1%, for the treatment of tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm) due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes* and *Trichophyton rubrum*.

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 the package insert, immediate container and carton labels) which was agreed to during our teleconference of March 9, 1999. We remind you of your commitment during our teleconference of March 9, 1999, to have the colored text and two foot diagrams submitted on your tube and carton labels and your consumer educational brochure replaced by black and white printing and diagrams at the next printing of these labels, or six months, which ever comes first. 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 20-980." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submissions dated March 3, and 5, 1999, respectively. This commitment, along with the completion date agreed upon, is listed below.

> Conduct the following as a Phase 4 Study within 1 year of NDA approval: Conduct a label comprehension study as a Phase 4 commitment to test consumers' comprehension of the terms "cures," "cures most," and "treats," or other such terminology that might be used for Indications/Uses in all labeling for Lamisil® Cream, 1%, NDA 20-980. In addition, test consumer's comprehension of labels with one versus two foot diagrams.

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. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. 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 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 send one copy to the Division of Dermatologic and Dental Drug Products 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 Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020 or Elizabeth F. Yuan, LTJG, R.Ph., Assistant Regulatory Management Officer, at (301) 827-2222.

Sincerely,

3/9/99

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

3/9/99

Debra L. Bowen, M.D.
Acting Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

Archival NDA 20-980 (with labeling)
HFD-540/Div. Files (with labeling)
HFD-222
HFI-20
HF-2/MedWatch (with labeling)
HFD-002/ORM/Lumpkin (with labeling)
HFD-101/L. Carter
HFD-40/DDMAC/Lechter (with labeling)
HFD-613/OGD (with labeling)
HFD-95/DDMS (with labeling)
HFD-830/DNDC Division Director (with labeling)
DISTRICT OFFICE (with labeling)
HFD-105/OFFICE DIR/DeLap (with labeling)
HFD-540/DIV DIR/Wilkin (with labeling)
HFD-540/DERM TL/Walker (with labeling) SW 3/5/99
HFD-540/MO/Vaughan (with labeling) [illegible] 3/5/99
HFD-540/CHEM TL/DeCamp (with labeling) WD 3/4/99
HFD-540/CHEM/Vidra (with labeling) ~~JV, 3/5/99~~
HFD-540/PHARM TOX TL/Jacobs (with labeling) A.J 3/4/99
HFD-540/PHARM TOX/Mainigi (with labeling) [illegible] 03/03/99
HFD-725/BIOSTAT TL/Srinivasan (with labeling) RS [illegible] 4, 99
HFD-725/BIOSTAT/Thomson (with labeling) SFT 03/03/99
HFD-880/BIOPHARM TL/Bashaw (with labeling) EM 3/4/99
HFD-520/MICRO TL/Sheldon (with labeling) TB 3/5/99
HFD-520/MICRO/Altaie (with labeling) S.S.A 03/03/99
HFD-160/MICRO TL/Cooney (with labeling)
HFD-160/MICRO/Hussong (with labeling) FHC 3/4/99 By E-mail
HFD-560/ACT DIV DIR/Bowen (with labeling) [illegible] 3/9/99
HFD-560/DEP DIV DIR/Katz (with labeling)
HFD-560/MO/Aurecchia (with labeling)
HFD-560/IDS TL/Lipnicki (with labeling) SRL 3-9-99
HFD-560/IDS/Mokhtari (with labeling)
HFD-550/CHEM TL/Patel (with labeling)
HFD-560/CHEM/Yaciw (with labeling)
HFD-560/SPM/Cook (with labeling)
HFD-560/PM/Yuan (with labeling)
HFD-540/SPM/Kozma-Fornaro (with labeling)
HFD-540/PM/Cross (with labeling)
Drafted by: fhc/February 19, 1999
filename: C:\word\lamisil\n20980ap.wpd

APPROVAL (AP)
PHASE 4 COMMITMENTS