CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S014

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine HCl

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: September 3, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-192/014

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S014

APPROVAL LETTER

30.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-192/S-014

SEP 3 1998

Novartis Pharmaceuticals Corporation
Attention: Robert J. Clark
59 Route 10
East Hanover, New Jersey 07936

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated March 30, 1998, received March 31, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine HCL) Cream, 1%.

The User Fee goal date for this application is September 30, 1998.

This supplemental application provides for approval for eliminating the minimum fill requirement for LAMISIL cream, 1%.

We have completed the review of this supplemental application and it is approved.

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., Project Manager, at (301) 827-2020.

Sincerely yours,

WD 9/3/98

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, DNDCIII
Division of Dermatologic and Dental
Drug Products (HFD-540)
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:

Original NDA 20-192
HFD-540/Div. Files
HFD-540/CSO/Cross
HFD-540/MO/Huene
HFD-540/Pharm/Mainigi
HFD-540/Chem/Vidra JV, 9-1-98
HFD-540/DeCamp
HFD-830/ONDCDivDir
HFD-92/DDM-DIAB
DISTRICT OFFICE
filename 20192

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S014

CHEMISTRY REVIEW(S)

JUN 10 1998

DIVISION OF DERMATOLOGICAL AND DENTAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-192 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 08-Jun-98

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
NDA 20-192/SCS-014	30-Mar-98	31-Jun-98	03-Apr-98
NDA 20-192/SNC-014	31-Mar-98	01-Apr-98	07-Apr-98

NAME & ADDRESS OF APPLICANT:

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936-1080
Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls
(973) 781-7005

DRUG PRODUCT NAME

Proprietary: Lamisil
Nonproprietary/USAN: terbinafine HCl

Code Names/#'s: 4021030/SF 86-327 ch
Chemical Type/ 1S
Therapeutic Class: Antifungal (topical)

ANDA Suitability Petition/DESI/Patent Status: NOT APPLICABLE!

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of Tinea Pedis/Interdigital & Plantar-Type S/Tinea Corporis/Cruris caused by Dermatophytes including Trichophyton.

DOSAGE FORM: Cream
STRENGTHS: 1%
ROUTE OF ADMINISTRATION: Topical
DISPENSED: ____ **Rx** __X__ **OTC**

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

(E)-N-(6,6-Dimethyl-2-hepten-4-ynyl)-N-methyl-1-naphthalenemethanamine hydrochloride

Molecular Formula: $C_{21}H_{25}N$ (free base)
$C_{21}H_{26}NCl$ (hydrochloride salt)

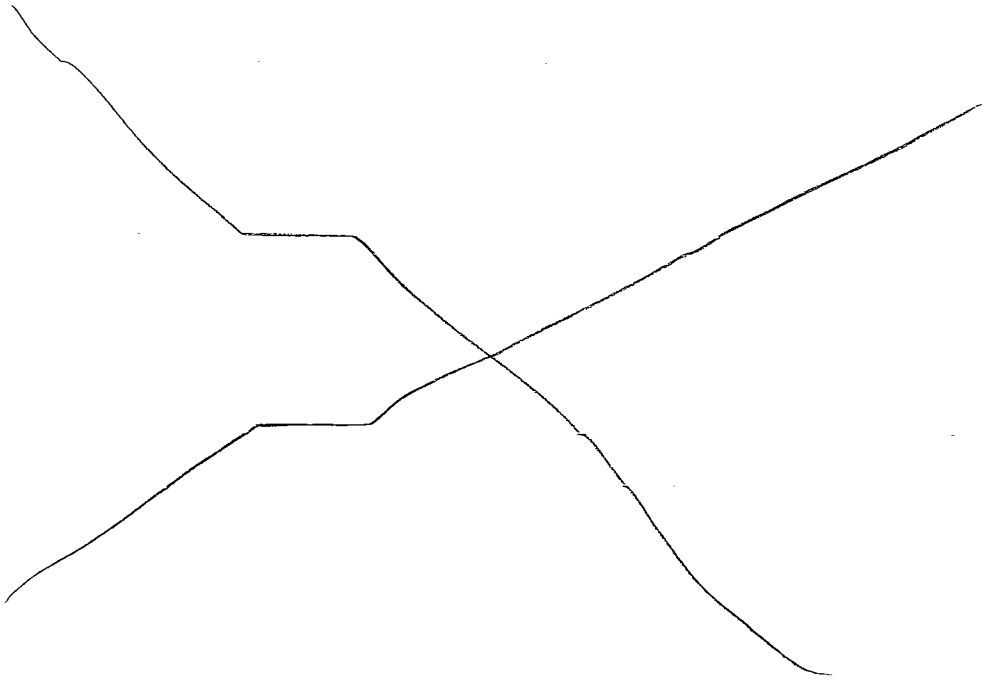
Molecular Weight: 291.44 (free base
327.79 (hydrochloride salt)

CAS No.: 78628-80-5

SUPPORTING DOCUMENTS:

NDA #20-192

REMARKS/COMMENTS:



CONCLUSIONS & RECOMMENDATIONS:

NDA Supplements 20-912/SCS-014 and 20-912/SNC-014 are both RECOMMENDED FOR APPROVAL. This recommendation is based upon acceptable minimum weight data and corrected FDA Forms.

James D. Vidra

James D. Vidra, Ph.D.
Review Chemist

cc: Orig. NDA #20-192
HFD-540/Division File
HFD-540/ProjMan/Cross
HFD-540/Pharm/Mainigi
HFD-540/MedOfF/Huene
HFD-540/Chem/Vidra
HFD-540/TeamLdr/DeCamp WDA 1/10/98
HFD-830/DivDir/Chen

filename: N20-192.S014