CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S012

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine HCl

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: April 3, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-192/012

CONTENTS

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

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APPLICATION NUMBER:

NDA 20-192/S012

APPROVAL LETTER

16.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 3 1997

NDA 20-192/S-012

Novartis Pharmaceuticals Corporation
Attention: Robert J. Clark, Senior Manager
Regulatory, Manufacturing and Controls
59 Route 10
East Hanover, New Jersey 07936

Dear Mr. Clark:

Please refer to your supplemental new drug application dated February 25, 1997, received February 27, 1997, 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 August 27, 1997.

The supplemental application provides for a new procedure used to reprocess a batch of failed Lamisil Cream. The procedure involved an [redacted] batch that required [redacted] resulting in a successfully reworked batch. When the reprocessed batch was subjected to both three month accelerated and short-term stability conditions, no significant differences were noted when compared to the drug product's specifications.

We have completed the review of this supplemental application and it is approved, effective as of the date of this letter.

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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

Sincerely yours,

WHD 4/3/97

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, DNDC III
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/F.H.Cross
HFD-540/Pharm/Mainigi
HFD-540/MedOff/Huene
HFD-540/Chem/Vidra VV, 3-24-97
HFD-540/TmLdr/DeCamp
HFD-830/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S012

CHEMISTRY REVIEW(S)

MAR 24 1997

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

NDA #: 20-192 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 3/16/97

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT SCS-012	2/25/97	2/27/97	3/7/97

NAME & ADDRESS OF APPLICANT:

Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936-1080
Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

DRUG PRODUCT NAME

Proprietary:	Lamisil
Nonproprietary/USAN:	terbinafine HCl
Code Names/#'s:	4030410
Chemical Type/	3S
Therapeutic Class:	Antifungal (topical)

ANDA Suitability Petition/DESI/Patent Status: Not Applicable!

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of Onychomycosis

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

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

(E)-N-(6,6-Dimethyl-2-hepten-4-yn-yl)-N-methyl-1-naphthalene methanamine

Molecular Formula:	$C_{21}H_{26}NCl$
Molecular Weight:	327.79
CAS No.:	78628-80-5

SUPPORTING DOCUMENTS:

NDA 20-192
NDA 20-192/SCS-011
2/7/97 Telephone Conversation

1 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-192 S 012

CONCLUSIONS & RECOMMENDATIONS:

NDA Supplement #20-192/SCS-012 is RECOMMENDED FOR APPROVAL based upon acceptable reprocessing and stability aging test results.

James D. Vidra

James D. Vidra, Ph.D.
Review Chemist

Attachment

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 WDJ 2/14/97
HFD-830/Chen

filename: N20192.s12

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 20-192, SCs-012
Lamisil Cream, 1%

DRAFT OF CHEMIST'S LETTER TO FIRM

Please prepare a response letter (Letter #NDA 111) using the following information.

1. NDA 20-192/SCS-012: Lamisil® (terbinafine HCl), Cream, 1%,
2. Sandoz Pharmaceuticals Corporation
   59 Route 10
   East Hanover, New Jersey 07936-1080
3. Robert J. Clark, Senior Manager, Regulatory Manufacturing & Controls
4. Date of Application: February 25, 1997
5. Provisions of Supplement:

This supplement was submitted to notify FDA of a new procedure used to reprocess a batch of failed Lamisil Cream. The procedure involved an [redacted] batch that required [redacted] resulting in a successfully reworked batch. When the reprocessed batch was subjected to both three month accelerated and short-term stability conditions, no significant differences were noted when compared to the drug product's specifications.

Thanks Connie!!!

1 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Administrative- 20-192
5012