CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S011

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine HCl

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: January 21, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-192/011

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Reviews / Information Included in this NDA Review.	
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Medical Review(s)	
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Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

NDA 20-192/S011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 21 1997

NDA 20-192/S-011

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

Dear Mr. Clark:

Please refer to your November 4, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine HCl) Cream, 1%.

The supplemental application provides for the establishment of a new procedure for reprocessing a batch of failed Lamisil Cream. The procedure combined [redacted] resulting in a successfully reworked batch. When the reprocessed batch was compared to historical batches by six regulatory methods and specifications, no significant differences were noted.

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
Consumer Safety Officer
(301) 827-2020

Sincerely yours,

WD 1/21/97

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, Jr.
HFD-540/Pharm/Mainigi
HFD-540/MedOff/Huene
HFD-540/Chem/Vidra 1-21-97
HFD-540/TeamLdr/DeCamp
HFD-830/C.Chen
HFD-80
DISTRICT OFFICE
HFD-232

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S011

CHEMISTRY REVIEW(S)

JAN 17 1997

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

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

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT SCS-011	11/4/96	11/8/96	11/14/96

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