CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S005

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine hydrochloride cream

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: October 17, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-192/S005

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
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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)	X

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APPLICATION NUMBER:
NDA 20-192/S005

APPROVAL LETTER

NDA 20-192/S-005

OCT 17 1995

Sandoz Pharmaceuticals Corporation
Attention: Ms. Norma Loeffler
59 Route 10
East Hanover, NJ 07936

Dear Ms. Loeffler:

Please refer to your April 13, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine hydrochloride cream) Cream, 1%.

The supplemental application provides for a new method to test for loss on drying of the drug substance.

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.

Sincerely yours,

Sahit Mokhtar-Reyale for DeCamp

Wilson H. DeCamp, Ph.D.
Supervisory Chemist
Division of New Drug Chemistry III
Division of Dermatologic and
Ophthalmologic Drug Products

cc: Orig. NDA 20-192
HFD-540/Division File
HFD-540/SCHEM/DeCamp Note for DeCamp 10/18/95
HFD-540/Chem/Higgins
HFD-540/MO/Chambers
HFD-540/Pharm/Mainigi
HFD-540/SPM/Cook
HFD-540/PM/Cross

FOR CONCURRENCE ONLY: JKWilkin 10/17/95

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S005

CHEMISTRY REVIEW(S)

D/R

OCT 16 1995

DIVISION OF TOPICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-192 **CHEM.REVIEW #:** 01 **REVIEW DATE:** 08-MAY-95

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT/SCS-05	13-APR-95	17-APR-95	04-MAY-95

NAME & ADDRESS OF APPLICANT: Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

DRUG PRODUCT NAME

Proprietary:	LAMISIL® Cream, 1%
Nonproprietary/USAN:	terbinafine HCl Cream
Code Names/#'s:	
Chemical Type/ Therapeutic Class:	

PHARMACOLOGICAL CATEGORY/INDICATION:

DOSAGE FORM:	cream
STRENGTHS:	1.0%
ROUTE OF ADMINISTRATION:	Topical
DISPENSED:	xxx **Rx** ____ **OTC**

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

REMARKS/COMMENTS:

This supplement was submitted to the subject of a New Drug Application to provide for a new method to test for loss on drying of the drug substance.

The current method used is a [redacted] Since terbinafine HCl [redacted] the [redacted] is not a suitable method for the determination of the loss on drying. The proposed method utilizes [redacted] where [redacted] will not be an issue.

It is evident that this method will improve the precision of the test results.

CONCLUSIONS & RECOMMENDATIONS:

This supplemental application is recommended for APPROVAL. Since the changes in this supplement are limited to the CMC section of the subject NDA, this supplement's approval letter may be signed by the supervisory chemist.

Janet G. Higgins 5/8/95

Janet G. Higgins
Review Chemist

cc: Orig. NDA 20-192
HFD-540/Division File
HFD-540/Higgins
HFD-540/MO/Chambers
HFD-540/Pharm/Mainigi
HFD-540/CSO/Turtil
HFD-540/SUPERVISOR/ De Camp 10/17/95
R/D Init by: SUPERVISOR

filename: **N20192.S05**

9W 10/16/95

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APPLICATION NUMBER:

NDA 20-192/S005

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date MAY 1 1995

NDA No. 20-192

Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

Attention: Norma P. Loeffler

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Lamisil Cream, 1%

NDA Number: 20-192

Supplement Number: S-005

Date of Supplement: April 13, 1995

Date of Receipt: April 17, 1995

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of ~~Anti-Infective~~ Drug Products
Center for Drug Evaluation and Research

FORM FDA 3217d (12/91)

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