CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S006

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine hydrochloride cream

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: November 2, 1995

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APPLICATION NUMBER:
NDA 20-192/S006

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)	X
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:
NDA 20-192/S006

APPROVAL LETTER

NOV - 2 1995

NDA 20-192/SCM-006

Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

Attention: John Taylor, Ph.D.
Director, Regulatory Manufacturing and Controls

Dear Dr. Taylor:

Please refer to your supplemental New Drug Application (NDA) dated June 9, 1995, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for LAMISIL® (TERBINAFINE HCl) Cream, 1.0%.

The supplemental application provides for an alternate testing facility, Sandoz, East Hanover, New Jersey site, to perform the USP antimicrobial preservative effectiveness test (APET).

We have completed our 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 set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

WD 11/2/95

Wilson H. DeCamp, Ph.D.
Supervisory Chemist
Division of New Drug Chemistry III
Office of New Drug Chemistry
Office of Pharmaceutical Science

cc: Orig. NDA 20-192
HFD-540/Division File
HFD-540/Higgins 10/2/95
HFD-540/MO/Chambers
HFD-540/Pharm/Mainigi
HFD-540/CSO/Cook
HFD-540/Wilkin
HFD-540/DeCamp

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APPLICATION NUMBER:

NDA 20-192/S006

CHEMISTRY REVIEW(S)

SEP 18 1995

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

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

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT/SCM-06	09-JUN-95	14-JUN-95	27-JUN-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 an alternate testing site for Lamisil Cream.

Currently the APET is performed at sandoz Pharmaceuticals in Lincoln, Nebraska. The applicant has proposed to add the Sandoz, East Hanover, New Jersey site as an alternate testing facility. The test method used by both facilities is the same, as described in USP general chapter <51>.

An EER was submitted in response to this application on June 28, 1995. The Office of compliance found this facility to be acceptable on July 28, 1995.

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 8/1/95

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
R/D Init by: SUPERVISOR

8/16/95

filename: **N20192.S06**

9/18/95

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APPLICATION NUMBER:

20-192/S006

MICROBIOLOGY REVIEW

JUL 17 1995

Consultative Review to HFD-540
MICROBIOLOGIST'S REVIEW OF SUPPLEMENT
DIVISION OF MEDICAL IMAGING, SURGICAL AND DENTAL DRUG PRODUCTS
July 17, 1995

NDA/Supplement Number: NDA 20-192/S-006 SCM

Document Date: June 9, 1995

Amendments and Others: N/A

Name and Address of Applicant: Sandoz Pharmaceutical Corp.
East Hanover, NJ 07936-1080

Name of Drug: Lamisil Cream 1%

Supplement Provides For: An alternate testing facility to perform the USP antimicrobial preservative effectiveness test (APET).

Pharmacological Category: Antifungal

Dosage Form: Topical cream

Method of Sterilization: Non-sterile

Comments:
The subject supplement is submitted to provide for an alternate testing site for the USP preservative effectiveness test (APET). the test is currently performed at Sandoz Pharmaceuticals in Lincoln, Nebraska. The supplement proposes to add the Sandoz, East Hanover, New Jersey site. The test is carried out according to the USP general chapter <51> currently and will be unchanged at the alternate testing facility.

Microbiology review for this type of change is unnecessary. An acceptable inspection report should be received prior to approval. This is consistent with recently agreed upon policy in the Center.

Conclusions and Recommendations: Recommend approval for the change in testing site, pending a satisfactory inspection report. The consulting Division should request the inspection.

Name: Peter H. Cooney, PhD
Supervisory Microbiologist, HFD-160

Signature: Peter H Cooney 7/17/95

cc: NDA 20-192
HFD-540/Turtil/Chem
HFD-~~160/Consult File~~/Cooney

HFD-540

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APPLICATION NUMBER:

NDA 20-192/S006

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JUN 22 1995

NDA No. 20-192

Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

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-006

Date of Supplement: June 9, 1995

Date of Receipt: June 13, 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,

for 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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