

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

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APPLICATION NUMBER:
NDA 20-192/S005

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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%.

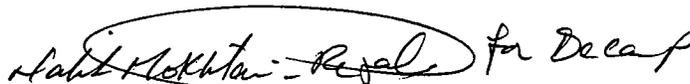
The supplemental application provides for a new method to test for loss on drying of the drug substance.

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,

A handwritten signature in cursive script, which appears to read "Wilson H. DeCamp". The signature is written in dark ink and is positioned above the typed name.

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

HFD-540/Chem/Higgins

HFD-540/MO/Chambers

HFD-540/Pharm/Mainigi

HFD-540/SPM/Cook

HFD-540/PM/Cross

NR for DeCamp 10/18/95

FOR CONCURRENCE ONLY: JKWilkin

JW 10/17/95

APPROVAL

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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

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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 ~~_____~~ Since terbinafine HCl ~~_____~~ the ~~_____~~ is not a suitable method for the determination of the loss on drying. The proposed method utilizes ~~_____~~ where ~~_____~~ 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/Turtill
HFD-540/SUPERVISOR/ De Camp *MS 10/14/95*
R/D Init by: SUPERVISOR

filename: N20192.S05

JW 10/16/95

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APPLICATION NUMBER:
NDA 20-192/S005

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

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

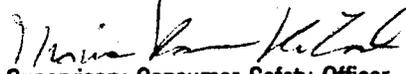
Date of Receipt: April 17, 1995

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 T&ICHL
Center for Drug Evaluation and Research