CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-192/S013

Trade Name: Lamisil Cream 1%

Generic Name: terbinafine HCl

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: June 30, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-192/013

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Medical Review(s)	
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Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

NDA 20-192/S013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 30 1997

NDA 20-192/S-013

Novartis Pharmaceuticals Corporation
Attention: Mr. Robert J. Clark
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Mr. Clark:

Please refer to your supplemental new drug application dated May 9, 1997, received May 17, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine HCl) Topical Cream, 1%.

The User Fee goal date for this application is November 17, 1997.

The supplemental application provides for deletion of a regulatory specification, i.e., the oil droplet specification. This approval is based upon a review of the necessary process and stability testing of both expired and current Lamisil Cream in 2, 15 and 30 gm tubes. However, this oil droplet test will be retained on an [redacted]

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 Cross, M.A., LCDR, Project Manager, at (301) 827-2020.

Sincerely yours,

W 6/30/97

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, DNDCIII
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/FCross
HFD-540/Pharm/Mainigi
HFD-540/MedOfcr/Huene
HFD-540/Chem/Vidra W, 6/30/97
HFD-540/ChemTmLdr/DeCamp
HFD-354/Yana Mille
HFD-830/DNDCIII Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-192/S013

CHEMISTRY REVIEW(S)

MAY 22 1997

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

NDA #: 20-192 **CHEM.REVIEW #:** 1 **REVIEW DATE:** 5/22/97

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT SCS-013	5/9/97	5/17/97	5/20/97
SUPPLEMENT SCS-012BC,	3/28/97	3/31/97	4/4/97
SUPPLEMENT NC	3/14/97	3/17/97	3/24/97

NAME & ADDRESS OF APPLICANT:

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936-1080
Robert J. Clark
Associate Director
Drug Regulatory Affairs

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, Original
NDA 20-192/SCS-012
2/11/97 Telecon