

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***  
**NDA 20-192/S012**

***Trade Name:*** Lamisil Cream 1%

***Generic Name:*** terbinafine HCl

***Sponsor:*** Sandoz Pharmaceutical Corporation

***Approval Date:*** April 3, 1997

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***APPLICATION NUMBER:***  
**NDA 20-192/012**

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**Reviews / Information Included in this NDA Review.**

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter</b>	
<b>Labeling</b>	
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	<b>X</b>
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	
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<b>Administrative/Correspondence Document(s)</b>	<b>X</b>

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**APPROVAL LETTER**



Food and Drug Administration  
Rockville MD 20857

APR - 3 1997

NDA 20-192/S-012

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

Dear Mr. Clark:

Please refer to your supplemental new drug application dated February 25, 1997, received February 27, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil (terbinafine HCl) Cream, 1%.

The User Fee goal date for this application is August 27, 1997.

The supplemental application provides for a new procedure used to reprocess a batch of failed Lamisil Cream. The procedure involved an \_\_\_\_\_ batch that required \_\_\_\_\_ resulting in a successfully reworked batch. When the reprocessed batch was subjected to both three month accelerated and short-term stability conditions, no significant differences were noted when compared to the drug product's specifications.

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.

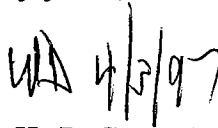
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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Frank H. Cross, Jr., M.A., LCDR, Project Manager, at (301) 827-2020.

Sincerely yours,



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  
HFD-540/Pharm/Mainigi  
HFD-540/MedOff/Huene  
HFD-540/Chem/Vidra *W, 3-24-97*  
HFD-540/TmLdr/DeCamp  
HFD-830/ONDC Division Director  
HFD-92/DDM-DIAB  
DISTRICT OFFICE

APPROVAL (AP)

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**CHEMISTRY REVIEW(S)**

MAR 24 1997

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

NDA #: 20-192      CHEM.REVIEW #: 1      REVIEW DATE: 3/16/97

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SUPPLEMENT SCS-012	2/25/97	2/27/97	3/7/97

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

<u>Proprietary:</u>	Lamisil
<u>Nonproprietary/USAN:</u>	terbinafine HCl
<u>Code Names/ #'s:</u>	4030410
<u>Chemical Type/</u>	3S
<u>Therapeutic Class:</u>	Antifungal (topical)

ANDA Suitability Petition/DESI/Patent Status: Not Applicable!

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of Onychomycosis

<u>DOSAGE FORM:</u>	Cream
<u>STRENGTHS:</u>	1%
<u>ROUTE OF ADMINISTRATION:</u>	Topical
<u>DISPENSED:</u>	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> 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 <sub>21</sub> H <sub>26</sub> NCl
Molecular Weight:	327.79
CAS No.:	78628-80-5

SUPPORTING DOCUMENTS:

NDA 20-192  
NDA 20-192/SCS-011  
2/7/97 Telephone Conversation

/ Page(s) Withheld

     ✓ § 552(b)(4) Trade Secret /  
Confidential

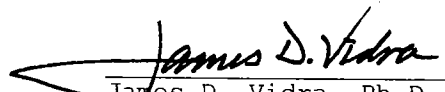
     § 552(b)(4) Draft Labeling

     § 552(b)(5) Deliberative Process



CONCLUSIONS & RECOMMENDATIONS:

NDA Supplement #20-192/SCS-012 is RECOMMENDED FOR APPROVAL based upon acceptable reprocessing and stability aging test results.

  
James D. Vidra, Ph.D.  
Review Chemist

Attachment

cc: Orig. NDA #20-192  
HFD-540/Division File  
HFD-540/ProjMan/Cross  
HFD-540/Pharm/Mainigi  
HFD-540/MedOff/Huene  
HFD-540/Chem/Vidra  
HFD-540/TeamLdr/DeCamp *wbs/24/97*  
HFD-830/Chen

filename: N20192.s12

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**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**



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