CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-749

CORRESPONDENCE

RECORD OF A FORWARD PLANNING MEETING

DATE: November 25, 1996

PARTICIPANTS FROM FDA:

Jonathan Wilkin, Division Director
Ella Toombs, Medical Officer
Jim Vidra, Chemist
Abby Jacobs, Senior Pharmacologist/Toxicologist
R. Srinivasan, Supervisor, Biostatistics
Steve Thomson, Biostatistican
Frank Cross, Project Manager
Robin Anderson, Project Manager
Mary Jean Kozma-Fornaro, Supervisory Project Manager

SUBJECT: **Lamisil Solution, NDA 20-749**

OBJECTIVE: To determine the fileability of NDA 20-749

The meetings were convened to determine the adequacy of NDA 20-749 for filing. All sections of the New Drug Application (NDA) were evaluated in terms of the general content and format requirements.

Contingent on the Biopharmaceutic portion of the application being fileable, the application was deemed fileable.

Subsequent to this meeting, it was determined that the Biopharmceutics portion of the application was deemed fileable.

Frank Cross, Jr., Project Manager, HFD-540

cc:

Orig NDA 20-749	HFD-160/MICRO/Sweeney
HFD-540	HFD-520/SMICRO/Sheldon
HFD-540/DIV DIR/Wilkin	HFD-520/MICRO/Altaie
HFD-540/MO/Toombs	HFD-725/DIR/Harkins
HFD-540/SCHEM/DeCamp	HFD-725/BIOSTAT SUPV/Srinivasan
HFD-540/CHEM/Vidra	HFD-725/BIOSTAT/Thomson
HFD-540/SRTOX/Jacobs	HFD-880/BIOPHARM SUPV/Bashaw
HFD-540/PHARM/Mainigi	HFD-540/PROJ MGR/Cross
HFD-160/MICRO SUPV/Cooney	

MEMORANDUM OF MEETING

NDA 20-749
Lamisil Solution, 1%
Page 1

Telecon Date: October 23, 1996 Time: 1300 Location: N229

Telecon for NDA 20-749, Lamisil Solution, 1%

Sponsor: Sandoz Pharmaceuticals Corporation

Meeting Chair: (CSO/Project Manager): Frank H. Cross, Jr., MA, LCDR

Meeting Recorder (CSO/Project Manager): Frank H. Cross, Jr., MA, LCDR

FDA Attendees, titles and offices:

Frank Cross, MA, LCDR, Regulatory Management Officer, DDDDP, HFD-540

Sponsor Attendees, titles and offices:

Stephenie Barba, Director, Drug Registration and Regulatory Affairs

Meeting Objectives:

1. Several more items are needed, i.e., six more 1.1's, an additional microbiology copy (1.10), and the proposed label on diskette in WP 5.2.

2. Resolving the question whether all manufacturing sites are ready for inspection at the time of the NDA submission.

Decisions (agreements) reached:

1. The sponsor agreed to supply the requested items as mentioned above.

2. The sponsor stated that all manufacturing sites are ready for inspection at the time of the NDA submission on October 17, 1996.

Unresolved issues or issues requiring further discussion: None

Signature, minutes preparer: _____
Concurrence Chair (or designated signatory): _____

cc:

Orig NDA 20-749
HFD-540
HFD-540/DIV DIR/Wilkin
HFD-540/DEP DIR/Katz
HFD-540/MO/Toombs
HFD-540/SR TOX/Jacobs
HFD-540/PHARMTOX/Mainigi
HFD-540/SCHEM/DeCamp
HFD-540/CHEM/Vidra
HFD-725/DIV DIR/Harkins
HFD-725/SBIOSTAT/Srinivasan
HFD-725/BIOSTAT/Thomson
HFD-880/SBIOPHARM/Bashaw
HFD-540/PM/Cross/rev1-10.30.96

TELECON MINUTES

Patricia McGovern
Assistant Director
Drug Regulatory Affairs

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

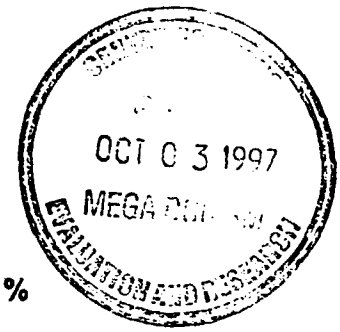
Tel 973-503-7384
Fax 973-503-6325
Internet:
pat.mcgovern@pharma.novartis.com

NOVARTIS

DUPLICATE

BL
ORIG AMENDMENT

September 26, 1997



Jonathan Wilkin
Director
Division of Dermatology and Dental Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room
Center for Drug Evaluation and Research
Corporate Building, 9201 Corporate Blvd.
Rockville, Maryland 20850

NDA No. 20-749

LAMISIL (terbinafine HCl solution) Solution 1%

RESPONSE TO FDA REQUEST FOR INFORMATION

Dear Dr. Wilkin

Reference is made to Novartis Pharmaceutical Corporation's pending New Drug Application for Lamisil (terbinafine hydrochloride solution) Solution, 1% (NDA 20-749) and to information provided to the Division on August 19, 1997 concerning the percent alcohol contained in this product. In addition, reference is made to a telephone conversation between the undersigned and Mr. Bob Clark of Novartis, and Mr. Frank Cross and Dr. James Vidra of FDA on October 1, 1997. During this conversation, Novartis was asked to provide revised container/carton draft labeling that includes the corrected percent alcohol. We are now providing the requested information. A desk copy of this submission, including a diskette containing electronic versions of the labels in Word Perfect 6.0, is being sent directly to Mr. Frank Cross, Project Manager for NDA 20-749.

If you have questions of comments concerning this submission, please call me at (973) 503-7384.

Sincerely,

Pat McGovern

Patricia McGovern
Assistant Director

Submitted in duplicate

Attachments

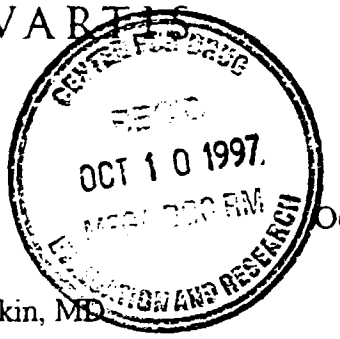
cc: Desk copy to Mr. Frank Cross

ORIGINAL

NOVARTIS

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325



ORIG AMENDMENT

October 9, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Ophthalmologic
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room
Center for Drug Evaluation and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA No. 20-749
LAMISIL® Solution, 1%
(terbinafine HCl solution)

RESPONSE TO FDA
REQUEST FOR INFORMATION

Dear Dr. Wilkin:

Reference is made to Novartis Pharmaceutical Corporation's pending New Drug Application for Lamisil (terbinafine hydrochloride solution) Solution, 1% (NDA 20-749) and to a telephone conversation between the undersigned and Mr. Frank Cross and Dr. Tony DeCamp of FDA on October 7, 1997. During this conversation, Dr. DeCamp stated that approval for the NDA could not be obtained without the prior submission of "mocked-up" container/carton labeling for this product. The requested labeling was prepared and Faxed to Dr. James Vidra, the review chemist for this project, on October 8, 1997. We are now officially submitting this documentation to the Division.

This submission includes approximately true-to-size color mock-ups of the spray bottle and dropper bottle labels and cartons. Please note that the clarity of the text on the final printed labeling will exceed that of the drafts. In order to facilitate the review of these labels, I have enclosed a copy of the FAX sent to Dr. Vidra, which contains black and white versions that have been enlarged.

If you have questions or comments concerning this submission, please contact me at (973) 503-7384.

Sincerely,

Patricia McGovern

Patricia McGovern
Assistant Director

PM/cos
Attachments
Submitted in Duplicate
cc: Desk copy to Dr. James Vidra

NOVARTIS

Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

ORIGINAL

SU
ORIG AMENDMENT

March 4, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Att: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL (terbinafine hydrochloride) Solution 1%

120 DAY SAFETY UPDATE

Dear Dr. Wilkin:

Reference is made to our pending New Drug Application for Lamisil® Solution, 1% (terbinafine hydrochloride solution) dated September 17, 1996. Pursuant to 21 CFR §314.50(d)(5)(vi)(b)(1), Novartis Pharmaceuticals corporation is now amending this pending application to provide the required update of safety data.

The attached update provides additional safety data on a total of 401 patients who were enrolled in two clinical trials subsequent to the cut-off date used for preparation of the original NDA database. One of these two trials, SFF 310, is now complete and the final clinical and statistical study report is included with this submission; the second trial, is still ongoing. This additional data confirm that Lamisil Solution is safe and well tolerated. There are no new emerging adverse experiences not previously known, nor are any known adverse experiences occurring at a greater frequency from that summarized in the original application. Therefore, there is no additional information that would change the proposed product labeling as submitted in the NDA on October 17, 1996.

If you have questions or comments concerning this submission, please contact the undersigned at (201) 503 7384.

ACTIVITIES COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

Sincerely,

Patricia McGovern

Patricia McGovern
Assistant Director

PM/dmh
Attachment
Submitted in duplicate

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAR 0 5 1997
MEGA DOC RM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: December 31, 1995.
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT	DATE OF SUBMISSION
Novartis Pharmaceuticals Corporation	March 4, 1997
ADDRESS *(Number, Street, City, State and ZIP Code)*	TELEPHONE NO. *(Include Area Code)*
59 Route 10 East Hanover, New Jersey 07936	(201) 503-7384
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER *(If previously issued)*
	20-749

DRUG PRODUCT

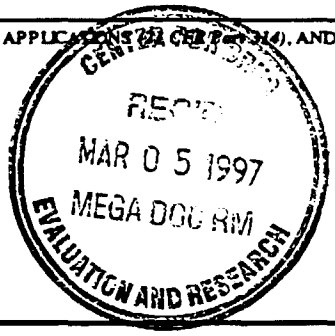
ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
terbinafine hydrochloride	LAMISIL®

CODE NAME *(If any)*	CHEMICAL NAME

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTHS (S)
Solution	Topical	1%

PROPOSED INDICATIONS FOR USE

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:



INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) *(21 CFR 314.55)*

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☒ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION
☐ ORIGINAL APPLICATION ☐ RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

CONTENTS OF APPLICATION	
This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Summary (21 CFR 314.50) (c))
	3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))
	4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
	b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))
	c. Labeling (21 CFR 314.50 (e) (2) (ii))
	i. draft labeling *(4 copies)*
	ii. final printed labeling (12 copies)
	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))
	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))
	7. Microbiology section (21 CFR 314.50 (d) (4))
	8. Clinical data section (21 CFR 314.50 (d) (5))
X	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
	10. Statistical section (21 CFR 314.50 (d) (6))
	11. Case report tabulations (21 CFR 314.50 (f) (1))
	12. Case reports forms (21 CFR 314.50 (f) (1))
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C 355 (b) (2) or (j) (2) (A))
	15. OTHER *(Specify)*

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211.
2. Labeling regulations in 21 CFR 201.
3. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.
4. Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.
5. Regulations on reports in 21 CFR 314.80 and 314.81.
6. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
Patricia McGovern, Assistant Director Drug Regulatory Affairs	Patricia McGovern	3/4/97

ADDRESS *(Street, City, State, ZIP Code)*	TELEPHONE NO. *(Include Area Code)*
59 Route 10 East Hanover, New Jersey 07936	(201) 503-7384

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10 EAST HANOVER, NEW JERSEY 07936-1080

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

October 17, 1996

Food and Drug Administration
Central Document Room
Park Building
1240 Parklawn Drive
Rockville, Maryland

NDA NO. 20-749

LAMISIL® (terbinafine hydrochloride) Solution , 1%

ORIGINAL NEW DRUG APPLICATION

Dear Sir or Madam:

In accordance with 21 CFR 314.50, Sandoz Pharmaceuticals Corporation herewith submits an original new drug application for Lamisil® Solution, 1% (terbinafine hydrochloride solution).

Lamisil Solution, 1% is indicated for topical treatment of the following dermatological infections: pityriasis versicolor due to *Malassezia furfur*, and tinea pedis (athlete's foot), tinea cruris (jock itch), or tinea corporis (ringworm), due to *Trichophyton rubrum, Trichophyton mentagrophytes*, or *Epidermophyton floccosum*. In the United States Lamisil® Solution, 1% was studied under IND No. which resides in the Division of Dermatologic and Dental Drug Products.

Nine adequate and well-controlled studies in the claimed indications are included in this NDA. These studies include two in pityriasis versicolor, four in tinea pedis (three pivotal and one supporting), and three in tinea corporis/cruris. A total of 1,666 patients were enrolled in these nine studies, 962 patients received Lamisil®, 351 received clotrimazole, and 353 received placebo. There is one ongoing study in tinea pedis which is briefly summarized in this application. In addition, six studies with Lamisil® Solution, 1% in indications not claimed at this time and eight studies with an unapproved formulation, Lamisil 1% DermGel, are included in this application to provide additional safety information.

Lamisil® Solution 1% is the second topical formulation of terbinafine hydrochloride that has been developed by Sandoz. Lamisil® (terbinafine hydrochloride) Cream 1% was approved on December 30, 1992 (NDA 20-192) for the treatment of tinea pedis and tinea corporis/cruris. In addition, Lamisil® (terbinafine hydrochloride tablets) Tablets

was approved on May 10, 1996 (NDA 20-539). Certain sections of this application are cross-referenced to NDA 20-192 or NDA 20-539.

As agreed during our Pre-NDA meeting on July 17, 1995, no CANDA has been prepared for this application. However, Sandoz will provide SAS (608) format datasets along with table formats to the Division under separate cover.

One half of the user fee total in the amount of was submitted to FDA on October 10, 1996 (No. 3095).

A certified copy of the Chemistry, Manufacturing and Controls Section (Item 3) of this new drug application is being provided to our district office in compliance with the pre-approval inspection requirements. An additional copy is being sent to FDA headquarters with this submission because all manufacturing operations for this product will be conducted overseas. Sandoz will be prepared for a pre-approval inspection of our facilities in Basel, Switzerland, where Lamisil Solution 1% will be produced, upon 30-days notice following the filing of this application.

Sandoz Pharmaceuticals Corporation considers the information contained within this application to be confidential, and its contents are not to be disclosed without express written consent.

If there are any questions or comments concerning this submission, please contact me at (201) 503-7548 or Ms. Patricia McGovern at (201)503 7384.

Sincerely,

Stephenie Barba
Director
Drug Registration and Regulatory Affairs

SB/dmh
Submitted in duplicate

cc: Mr. Matthew Lewis, Newark District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: December 31, 1995.
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314).*

NAME OF APPLICANT
Sandoz Pharmaceuticals Corporation

DATE OF SUBMISSION

ADDRESS *(Number, Street, City, State and ZIP Code)*
59 Route 10
East Hanover, NJ 07936

TELEPHONE NO. *(Include Area Code)*
(201) 503-7548

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER *(If previously issued)*
20-749

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
terbinafine hydrochloride	Lamisil®

CODE NAME *(If any)*	CHEMICAL NAME

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTHS (S)
Solution	Topical	1%

PROPOSED INDICATIONS FOR USE
Topical treatment of tinea pedis, tinea cruris, and tenia corporis caused by Trichophyton rubrum, Epidermophyton floccosum, or Trichophyton mentagrophytes, and in the treatment of pityriasis versicolor due to Pityrosporum species.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

DMF NDA No. 20-192, 20-539 IND No.

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☒ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) *(21 CFR 314.55)*

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☐ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION
☒ ORIGINAL APPLICATION ☐ RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

ORIGINAL

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

October 21, 1996

NEW CORRESPONDENCE

NDA 20-749

Jonathan Wilkin, MD, Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

Lamisil® (terbinafine hydrochloride) Solution 1%

GENERAL CORRESPONDENCE

Dear Dr. Wilkin:

Reference is made to the pending New Drug Application for Lamisil Solution 1% (terbinafine hydrochloride solution) (NDA 20-749) submitted on October 17, 1996. Reference is also made to our pre-NDA meeting for this product held on July 17, 1995 and a telephone conversation between Dr. Srinivasan and Ms. Stephenie Barba of Sandoz of October 17, 1996. As agreed, Sandoz is now providing SAS datasets and corresponding documentation for six Lamisil 1% Solution studies: SFF 301, SFF 303, SFF 305, SFF 309, SFF 351, and SFF 353. Raw data files and analysis data files are included for each of these studies.

Should you need additional information or have questions about this submission, please call me at (201) 503-7384.

Sincerely,

Stephenie Barba
for

Patricia McGovern
Assistant Director
Drug Registration and Regulatory Affiars

PM/dmh
Submitted in duplicate
cc: Mr. Frank Cross Rm N229 - Desk Copy

NEW CORRESPONDENCE

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

October 25, 1996

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD -540
Office of Drug Evaluation V
Att: Document Control Room 12B-30
Center for Drug Evaluation and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA NO. 20-749

LAMISIL® (terbinafine hydrochloride) Solution 1%

GENERAL CORRESPONDENCE

Dear Dr. Wilkin:

Reference is made to the pending New Drug Application for Lamisil Solution 1% (terbinafine hydrochloride solution) (NDA 20-749) submitted on October 17, 1996. Reference is also made to a telephone conversation between Mr. Frank Cross of FDA and Ms. Stephenie Barba of Sandoz on October 23, 1996. As agreed, Sandoz is now submitting draft labeling for this product on diskette, and a copy of the Microbiology section (section 7) and microbiology information from the Chemistry, Manufacturing and Controls section (section 3) of the NDA in a white "Microbiology" binder.

Should there be any questions with respect to this correspondence, please call me at (201) 503-7384.

Sincerely,

Patricia McGovern

Patricia McGovern
Associate Director

PM/dmh
Submitted in duplicate
Attachments
cc: Mr. Frank Cross with disk

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080

SANDOZ

NEW CORRESPONDENCE

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL. 201 503 7500
FAX 201 503 6325

November 4, 1996

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room
Center for Drug Evaluation and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA NO. 20-749

LAMISIL® (terbinafine hydrochloride Solution 1%

GENERAL CORRESPONDENCE

Dear Dr. Wilkin:

Reference is made to Sandoz's pending new drug application for Lamisil Solution 1% (NDA No. 20-749). Reference is also made to a telephone conversation on December 2, 1996 between the undersigned and Dr. Ella Toombs of FDA. In this discussion, Dr. Toombs requested that Sandoz provide tables of efficacy and safety data from the clinical studies for Lamisil Solution 1% in electronic form.

As requested, I am sending a diskette containing Word Perfect files of Sections 2H.3, Overview of Controlled Clinical Studies, and 2H.6, Safety Summary - General Safety Considerations from the NDA directly to Dr. Toombs. These files contain tables with efficacy and safety data that may be of use during the review process. In the efficacy tables provided the results are broken down by study and are also pooled by indication. All of the safety data is pooled. For this reason, we are preparing additional diskettes with safety data from each of the individual study reports. This additional information will provided as soon as possible.

Should there be any questions or comments concerning this information, please contact me directly at (201) 503-7384.

Sincerely,

Patricia McGovern

Patricia McGovern
Assistant Director

PM/dmh
Submitted in duplicate
cc: Mr. Frank Cross
Ella Toombs, MD with diskette

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

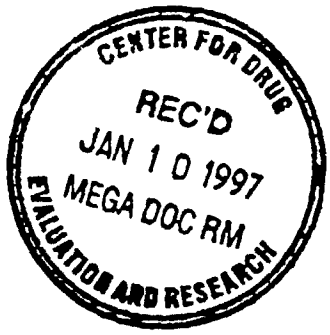
ORIGINAL

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10 EAST HANOVER, NEW JERSEY 07936-1080

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS
TEL 201 503 7500
FAX 201 503 8025

NEW CORRESPONDENCE



January 9, 1997

Jonathan Wilkin, M. D.
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room 12B-30
Center for Drug Evaluation and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA NO. 20-749

LAMISIL ® (terbinafine hydrochloride)Solution 1%

General Correspondence

Dear Dr. Wilkin:

Reference is made to Sandoz's pending New Drug Application for Lamisil Solution 1% (NDA 20-749). Reference is also made to telephone conversations between the undersigned and Mr. Frank Cross and Dr. Ella Toombs of FDA on January 2, 1997 and January 6, 1997, during which Sandoz was asked to provide safety and efficacy data tables from clinical studies contained in the NDA in electronic format for use during the clinical review. Diskettes containing the appropriate tables from two of the nine clinical studies in the three claimed indications, SFF 353 and SFF 351, are being sent directly to Mr. Cross. For reference purposes, I have also enclosed hard copy of the electronic files provided. We are working to prepare electronic versions of tables from the remaining seven studies (SFF 305, SFF 301, SFF 309, SFF 104, SFF 303, SFF 105 and SFF 108) and will provide these tables to the Division within the next two weeks.

If you have questions or comments concerning this correspondence, please contact me at (201) 503-7384.

Sincerely,

Patricia McGovern
Assistant Director

PM/dmh
Submitted in duplicate
cc Frank Cross (w/attachment, diskettes)

ORIGINAL

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10 EAST HANOVER NEW JERSEY 07936 USA

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

NEW CORRESPONDENCE

January 20, 1997

Jonathan Wilkin, M. D.
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL ® (terbinafine hydrochloride)Solution 1%

General Correspondence

Dear Dr. Wilkin:

Reference is made to Sandoz's pending New Drug Application for Lamisil Solution 1% (NDA 20-749). Reference is also made to telephone conversations between the undersigned and Mr. Frank Cross and Dr. Ella Toombs of FDA on January 2, 1997 and January 6, 1997, during which Sandoz was asked to provide safety and efficacy data tables from clinical studies contained in the NDA in electronic format for use during the clinical review. Diskettes containing the appropriate tables from two of the nine clinical studies in the three claimed indications, SFF 353 and SFF 351, were sent directly to Mr. Cross on January 9, 1997. At this time we are providing electronic versions of tables from the remaining seven studies (SFF 305, SFF 301, SFF 309, SFF 104, SFF 303, SFF 105 and SFF 108). For reference purposes, I have also enclosed hard copy of the electronic files provided.

If you have questions or comments concerning this correspondence, please contact me at (201) 503-7384.

Sincerely,

Patricia McGovern
Assistant Director

PM/dmh
Submitted in duplicate
cc Frank Cross (w/attachment, diskettes)

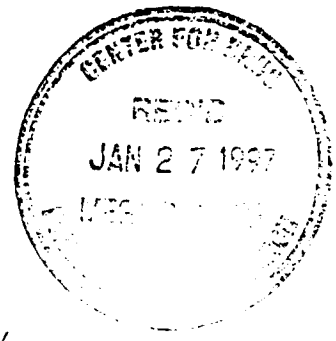
SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10 EAST • HANOVER, NEW JERSEY 07936 • USA

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

BM
NDA ORIG AMENDMENT



January 22 1997

Jonathan Wilkin
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn. Document Control Room 12B-30
Center for Drug Evaluation and Reserach.
5600 Fishers Lane
Rockville. Maryland 20850

NDA NO. 20-749

LAMISIL ® (terbinafine hydrochloride)Solution 1%

Response to Request For Information

Dear Dr. Wilkin:

Reference is made to Sandoz' pending New Drug Application for Lamisil Solution, 1% (NDA 20-749). Reference is also made to my January 9, 1997 telephone conversation with Mr. Frank Cross during which he requested that we provide the following additional information:

1 Table (similar in format to Table 2H.6) showing eradication rate by organism (including microsporum canis) for tinea corporis/cruris.

2. An analysis of total signs and symptoms score (TSSS) at baseline in relation to Effective treatment (This information was presented for study SFF 303, but not for Studies SFF 105 and SFF 108).

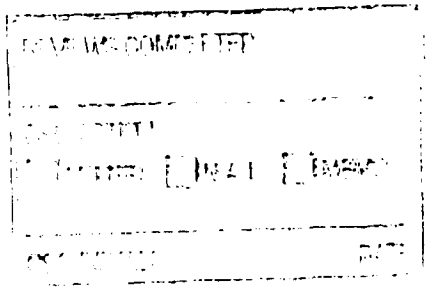
The requested information is appended. If you have any questions or comments, please contact me directly at (201) 503-7384.

Sincerely,

Patricia McGovern
Assistant Director

PM/dmh
Submitted in duplicate

cc: Mr. Frank Cross (w/attachment)



DUPLICATE

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10 EAST HANOVER NEW JERSEY 07936-1080

SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

February 14, 1997

DM
NDA ORIG AMENDMENT

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-749

Lamisil Solution 1%
(terbinafine hydrochloride solution

FDA Request for Information

Dear Dr. Wilkin:

Reference is made to Sandoz's pending New Drug Application for Lamisil Solution 1% (NDA 20-749) and to a telephone conversation between the undersigned and Mr. Frank Cross of FDA on January 28, 1997. During this discussion, Mr. Cross requested that Sandoz provide analyses of the mean reduction in Total Signs and Symptoms Score (TSSS) for lamisil and placebo for two studies, SFF 105 and SFF 108, supporting the Tinea corporis/cruris indication. We are now providing this analysis.

If you have questions or comments concerning this submission, please contact me at (201) 503-7384.

Sincerely,

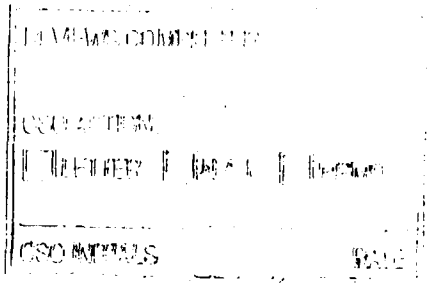
Pat McGovern

Patricia McGovern
Assistant Director

Submitted in duplicate

Attachment

cc: Mr. Frank Cross (w/att.)



Lamisil Solution 1% (terbinafine hydrochloride solution)
NDA 20-749

Reduction in Mean Total Signs and Symptoms Score for SFF 105 and SFF 108

In studies SFF 105 and SFF 108, the mean total signs and symptoms score (TSSS) at Baseline was 6.6 and 6.9 in the Lamisil groups, and 6.4 and 7.1 in the placebo groups, respectively. As displayed in the attached tables, at End of Study (equals last observation post-baseline) in these studies, Lamisil had reduced the Baseline mean TSSS by 5.1 and 5.6, whereas placebo had reduced the Baseline mean TSSS by 2.0 and 1.7, respectively. The superiority of Lamisil compared to placebo for mean reduction in TSSS from Baseline to End of Study was statistically significant ($P<0.0001$, Van Elteren test using center as stratification factor), in each of the studies.

These results are similar to the other key tinea corporis/cruris study, SFF 303, and to the results of the 3 key tinea pedis studies, thus demonstrating consistent and marked efficacy across the different tinea corporis/cruris studies and between the dermatophyte indications of tinea pedis and tinea corporis/cruris.

Study SFF108: Mean reduction in TSS at End Of Study (ITT Population)

Visit		1% Lamisil solution	Placebo	p-value
EOS	N	35	35	
	mean	5.63	1.66	# < 0.0001
	Standard deviation	2.70	3.36	
	median	6.00	1.00	
	min	-3.00	-4.00	
	max	10.00	9.00	

p-value results from Van Elteren test
A negative reduction indicates a worsening condition

Program source: SCORECHG.SAS Output: SCORECHG.TBL by Sandoz France 10FEB97 - 14:51

Study SFF105: Mean reduction in TSS at End Of Study (ITT Population)

Visit		1% Lamisil solution	Placebo	p-value
EOS	N	26	26	
	mean	5.12	1.96	# <0.0001
	Standard deviation	2.53	2.79	
	median	6.00	1.50	
	min	-2.00	-2.00	
	max	8.00	8.00	

p-value results from the Van Elteren test
A negative reduction indicates a worsening condition

Program source: SCORECHG.SAS Output: SCORECHG.TBL by Sandoz France 10FEB97 - 13:56

ORIGINAL

NOVARTIS

Michael S. Perry, D.V.M., Ph.D.
Vice President

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs North America
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7358
Fax 201 503 8364

NC
NEW CORRESP

March 19, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-749
LAMISIL® Solution, 1% (terbinafine hydrochloride solution)

CHANGE IN COMPANY NAME

Dear Dr. Wilkin:

Effective January 1, 1997, Sandoz Corporation (Sandoz) merged into Ciba-Geigy Corporation (Ciba), which changed its name to Novartis Corporation. In addition, Novartis Corporation contributed assets relating to the business of the former Ciba Pharmaceuticals Division, including New Drug Applications, to Sandoz Pharmaceuticals Corporation, which changed its name to Novartis Pharmaceuticals Corporation ("Novartis"). Therefore, effective with this letter, all future correspondence to the LAMISIL® Solution, 1% (terbinafine hydrochloride solution), NDA No. 20-749 file will be from Novartis.

Sincerely,

Michael S. Perry, DVM, PhD
Vice President
Drug Regulatory Affairs
North America

REVIEWS COMPLETED

DATE

/kam
Submitted in duplicate

cc: Richard Lipov, Database Management
Mary Jean Fornaro, Supervisory CSO

RECD
MAR 2 0 1997
HFD-

RIGINAL

NEW CORRESP

NOVARTIS

59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

June 16. 1997

Mr. Frank Cross
Regulatory Management Officer
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Office of Drug Evaluation and Research
Corporate Building, 9201 Corporate Blvd.
Rockville, MD 20850

NDA NO. 20-749

LAMISIL® (terbinafine hydrochloride solution) Solution 1%

REQUESTED INFORMATION

Dear Mr. Cross:

Reference is made to Novartis' pending New Drug Application for Lamisil (terbinafine hydrochloride solution) Solution, 1% and to our telephone conversation of earlier today in which you requested a second electronic copy of the draft labeling for this product. I am now sending you a 3.5" computer disk containing the draft labeling in Word Perfect 6.1 format.

If you have any questions about this correspondence or have difficulty utilizing the electronic file provided, please contact me directly at (201) 503-7384

Sincerely,

Pat McGovern

Patricia McGovern
Assistant Director

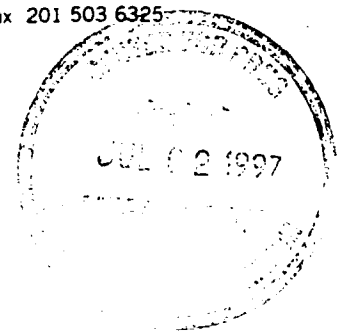
PM/dmh
Enc. - disk

DUPLICATE

NOVARTIS

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325



June 30, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL SOLUTION 1%
(terbinafine hydrochloride solution)

Requested Information

NEW CORRESPONDENCE

Dear Dr. Wilkin:

Reference is made to Novartis's pending New Drug Application for Lamisil® (terbinafine hydrochloride solution) Solution, 1% and to a telephone conversation between the undersigned and Mr. Frank Cross of FDA on June 30, 1997, during which Novartis was asked to provide an additional copy of the draft labeling for this product in electronic form. A diskette containing the draft labeling in Word Perfect 6.1 format is being sent directly to Mr. Cross. As requested, all soft-hyphenation formatting has been removed from the file.

Should there be any questions or comments concerning this submission, please contact me directly at (973) 503-7384.

Sincerely

Patricia McGovern

Patricia McGovern
Assistant Director

PM/dmh
Attachment
Submitted in duplicate
cc: Mr. Frank Cross with disk copy

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

ORIGINAL

East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

NOVARTIS

August 29, 1997

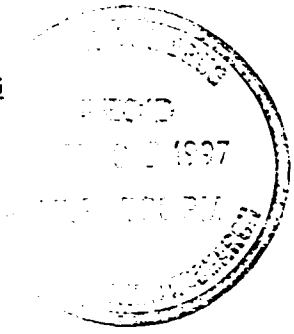
ORIG AMENDMENT

Jonathan Wilkin, MD
Director
Division of Dermatologic and Ophthalmologic
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room
Center for Drug Evaluation
and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA No. 20-749
LAMISIL® Solution 1%
(terbinafine HCl solution)

ADMENDMENT TO A PENDING NEW DRUG APPLICATION

CHEMISTRY



Dear Dr. Wilkin:

Please refer to the telephone conversations and subsequent facsimile communications, between myself, Ms Patricia McGovern of Novartis Pharmaceuticals Corporation and Dr. James Vidra (reviewing chemist), Mr. Frank Cross (project manager) at the Dermatologic and Dental Drug Division, that took place on July 18th and August 5th 1997.

These telephone conversations and telefaxes were in reference to the labeled quantity of ethanol that is present in the drug product for above cited application. Please also find enclosed copies of the telefaxes that were sent to the Agency on the above cited dates. Please note that as per the August 5th telefax, the labeled quantity of ethanol will be reported as 28.7% (V/V).

Please finally note that as per the August 13, 1997 telephone conversation between Ms. Patricia McGovern of Novartis Pharmaceuticals Corporation and Mr. Frank Cross of the Dermatologic and Dental Drug Division the exact copies of the above cited telefaxes are being submitted to file of the pending New Drug Application.

Please note that all final printed labeling will be updated to reflect this change.

A certified copy of this supplement is being provided to our local district office in compliance with preapproval inspection requirements. If you have questions or comments, please contact me at (201) 503-7005.

Sincerely,

Robert J. Clark
Associate Director,
Drug Regulatory Affairs

Attachments
Submitted in duplicate
cc: Ms. Regina Brown, North Brunswick Preapproval Inspection Office

NOVARTIS

DUPLICATE

NC

NEW CORRESP

September 9, 1997

Mr. Frank Cross
Division of Dermatological and Dental
Drug Products/HFD-540
Office of Drug Evaluation V Lane
Attn: Document Control Room 12B-30
Center for Drug Evalation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-749
Lamisil (terbinafine HCl Solution) Solution

Dear Mr. Cross:

As discussed during our telephone conversation this morning, this letter will confirm that the following foreign pivotal studies, conducted to support the approval of the Lamisil Solution NDA (#20-749), were sponsored and funded by Novartis Pharma (formerly Sandoz Pharma):

P. Versicolor	SFF 305
T. Pedis	SFF 301; SFF 309
T. Corporis/Cruris	SFF 303; SFF 108

Should you have any questions, please do not hesitate to contact me at (973) 503-7548.

Sincerely,

Stephenie Barba
Executive Director
Drug Regulatory Affairs

DUPLICATE

NEW CORRESP

Stephenie Barba
Executive Director
Drug Regulatory Affairs

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

Tel 973-503-7548
Fax 973-503-6325
Internet: stephenie.barba
@pharma.novartis.com

NOVARTIS

September 15, 1997

Mr. Frank Cross
Division of Dermatological and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Att.: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL(terbinafine
HCl Solution) Solution

Response to FDA Request

Dear Mr. Cross:

As per your request, I am officially submitting the appended information to NDA 20-749, Lamisil (terbinafine hydrochloride solution) Solution. This information was previously faxed to you on September 8, 1997. Should you have any comments or questions, please do not hesitate to contact me.

Sincerely,

Stephenie Barba
Executive Director

SB/dmh
Attachment

Executive Director
Drug Regulatory
Affairs

58 Route 10
East Hanover, NJ 07936-1080

Tel 973 503 7548
Fax 973 609 6325

NOVARTIS

Fax

Attention Mr. Frank Cross

Fax no. (301) 827 - 2075
Number of pages 1 including cover page

Date September 8, 1997

Concerning **Lamisil Solution - NDA 20-749**

Dear Frank,

As we discussed, the following key studies were conducted in the United States and were conducted under IND

P. Versicolor	SFF 353
T. Pedis	SFF 351
T. Corporis/Cruris	SFF 105

Additionally, Study SFF 104 (T. Pedis), which is a supporting study, was conducted under IND

We would also like to confirm that since Lamisil solution is a not a new chemical entity and since clinical studies were required to support this approval, this product would be entitled to receive 3 years exclusivity. However, as we discussed, the patents for Lamisil extend beyond this period of exclusivity.

Please contact me if you have questions.

Best regards,

Stephenie Barba

Patricia McGovern
Assistant Director
Drug Regulatory Affairs

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

Tel 973-503-7584
Fax 973-503-6325
Internet:patricia.mcgovern
@pharma.novartis.com

NOVARTIS

September 16, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/ -540
Office of Drug Evaluation
Attn: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL (terbinafine HCl solution) Solution 1%

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to Novartis' pending New Drug Application for Lamisil Solution 1% (NDA 20-749) and to recent telephone conversations between the undersigned and FDA representatives Mr. Frank Cross and Dr. James Vidra.

These conversations were specific to the functionality of the spray pump which is described in the New Drug Application. Dr. Vidra requested that information be provided to the NDA in support of the claim that the spray pump can be operated in either the upright or the inverted position as per the application.

We are now providing data which supports the use of the pump in both positionsand information from the manufacturer which describes the dual functionality of the pump. Please note that whereas the manufacturer considers the spray bottle to be a metered dose delivery system, Novartis has not made this claim for the product.

If you have questions or comments concerning this submission, please contact the undersigned at (973) 503-7384

Sincerely,

P McGovern

Patricia McGovern

PM/dmh

Submitted in Duplicate

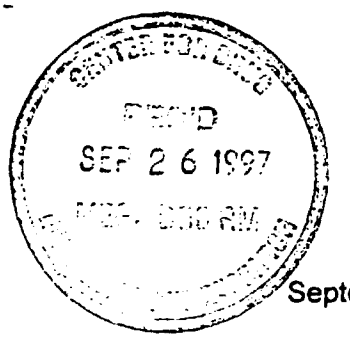
Attachments

Assistant Director
Drug Regulatory Affairs

59 Route 10
East Hanover, NJ 07936

Tel 973-503-7584
Fax 973-503-6325
Internet:patricia.mcgover...
@pharma.novartis.com

NOVARTIS



September 23, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation
Attn: Document Control Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-749

LAMISIL (terbinafine HCl solution) Solution 1%

Response to FDA Request For Information

Dear Dr. Wilkin:

Reference is made to Novartis Pharmaceuticals Corporation's pending New Application for Lamisil Solution 1% (NDA 20-749) and to documentation submitted to the Division on September 16, 1997 at FDA request which provided data demonstrating that the spray bottle described in the NDA can be operated in either the upright or inverted position. Two pages of data were inadvertently omitted from this submission. We are now providing a complete copy of the supporting documentation originally submitted on September 16, 1997.

Sincerely,

Patricia McGovern

PM/dmh

Attachments

Submitted in Duplicate

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

NOVARTIS

October 7, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Ophthalmologic
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room
Center for Drug Evaluation
and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA No. 20-749
LAMISIL® Solution, 1%
(terbinafine HCl solution)

RESPONSE TO FDA QUESTIONS

CHEMISTRY

Dear Dr. Wilkin:

Reference is made to the October 1, 1997 telephone conversation between representatives of Novartis Pharmaceuticals Corporation (Mr. Robert Clark and Ms. Patricia McGovern) and Mr. Frank Cross and Dr. Jim Vidra at the Dermatologic and Dental Drug Product Division.

During that telephone conversation Dr. Vidra mentioned that he would be most interested to see the schematic diagrams of the containers that are referenced in the above cited NDA. Dr. Vidra also mentioned that he would like to see Certificates of Analysis from the manufactures of the drug product containers as well as any Drug Master File references for the primary packaging materials.

Therefore please find enclosed the schematic diagrams (with dimensions) for the dropper and spray bottles. The other materials (as available) will also be forwarded to the FDA when they are available.

If you have questions or comments, please contact me at (201) 503-7005.

Sincerely,

Robert J. Clark
Drug Regulatory Affairs

Submitted in duplicate
Sent via TELEFAX

CC: Mr. Frank Cross
Dr. James Vidra

NC

NEW CORRESP

NOVARTIS

DUPLICATE

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

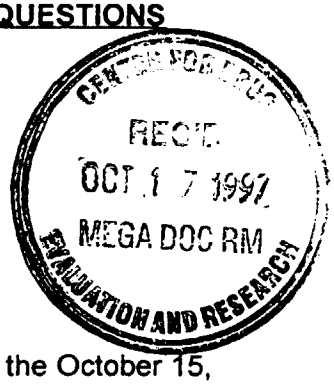
October 16, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Ophthalmologic
Drug Products/HFD-540
Office of Drug Evaluation V
Document Control Room
Center for Drug Evaluation
and Research
Corporate Building, 9201 Corporate Boulevard
Rockville, Maryland 20850

NDA No. 20-749
LAMISIL® Solution 1%
(terbinafine HCl solution)

RESPONSE TO FDA QUESTIONS

CHEMISTRY



Dear Dr. Wilkin:

Please refer to the above cited New Drug Application. Please also refer to the October 15, 1997 telephone conversation with Dr. Jim Vidra and Mr. Frank Cross of the Dermatologic and Dental Drug Product Division and representatives from Novartis Pharmaceuticals Corporation (the undersigned and Ms. Patricia McGovern). During that telephone conversation Dr. Vidra and Mr. Cross had requested that certain information in the container closure system section (from pages 3-249 - 3-299) of the above cited NDA be re-presented in tabular format.

Therefore, please find enclosed the above requested information. Please also note that this information was faxed to the Division on Tuesday October 15th. In addition to information which was contained in the original NDA this update contains references to the part number (which was corrected) of the complete pump assembly from Pfeiffer. Also included is a brief synopsis of the extractables test procedure that will be used for the release container closure materials and a list of manufacturers (names and addresses) which are referenced in the container closure section of the NDA.

If you have any questions and or comments, I can be reached at 976 503-7005.

Sincerely,

Robert J. Clark
Drug Regulatory Affairs

Submitted in duplicate

NC / Phase 4

NOVARTIS NEW CORRESP DUPLICATE

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

October 16, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Contral Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-749
LAMISIL® Solution, 1%
(terbinafine HCl solution)

PHASE IV COMMITMENT

Dear Dr. Wilkin:

Reference is made to Novartis Pharmaceutical Corporation's pending New Drug Application for Lamisil (terbinafine hydrochloride solution) Solution, 1% (NDA 20-749) the attached Fax from the Division received on October 16, 1997. This Fax provides a list of Phase IV commitments proposed by the agency to obtain approval of this product.

Novartis agrees to comply with all three of the proposed Phase IV commitment as stated in the attached Fax.

If you have questions or comments concerning this submission, please contact me at (973) 503-7384.

Sincerely,

Patricia McGovern

Patricia McGovern
Assistant Director

PM/cos
Attachments
Submitted in Duplicate
cc: Desk copy to Mr. Frank Cross

NOVARTIS

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

October 17, 1997

Jonathan Wilkin, MD
Director
Division of Dermatologic and Dental
Drug Products/HFD-540
Office of Drug Evaluation V
Attn: Document Contral Room 12B-30
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-749
LAMISIL® Solution, 1%
(terbinafine HCl solution)

Dear Dr. Wilkin:

Please refer to Novartis Pharmaceuticals Corporation's pending New Drug Application for Lamisil (terbinafine hydrochloride solution) Solution, 1% (NDA 20-749) and to the proposed labeling for this product Faxed to Novartis by the Division on October 16, 1997 and amended on October 17, 1997. Novartis accepts this labeling as proposed. Should you have any questions, please contact me at (973) 503-7384.

Sincerely,

Patricia McGovern

Patricia McGovern
Assistant Director

PM/cos
Submitted in Duplicate
Faxed to: Mr. Frank Cross