CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20-980

CORRESPONDENCE

NDA ORIG AMENDMENT

BL

NOVARTIS

Christine Babiuk, Ph.D.
Associate Director,
Regulatory Affairs

Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, NJ 07901-1312

Tel 908 598 7816
Fax 908 273 2869

DUPLICATE

October 27, 1998

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, MD 20857

NDA # 20-980
Terbinafine Hydrochloride Cream, 1%

Rx-to-OTC Switch NDA: Protocol for Label Comprehension Study

Dear Dr. Wilkin:

Reference is made to our telephone conference with the Divisions of Dermatologic and Dental Drug Products and Over-the-Counter Drug Products on October 1, 1998. At that time, we had agreed to conduct a label comprehension study. Attached is the protocol for the bifurcated label comprehension study and the carton label as well as the package insert being tested.

Due to the tight time frame, we have moved along with the study in parallel with sending you copies of the protocol, carton label and package insert so that we would not run the risk of submitting a major amendment after December 30, 1998. As discussed during the telephone conference, the primary endpoint of the study is demonstrating that the consumer can appropriately choose the duration of treatment based on the affected anatomical region of the foot.

Please contact the undersigned with any comments or questions.

Sincerely,

Christine Babiuk

Christine Babiuk, PhD
Associate Director, Regulatory Affairs
Novartis Consumer Health, Inc.

Attachment:
Submitted in duplicate
cc: Frank Cross by facsimile (301-827-2091)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER
20-980

APPLICANT INFORMATION

NAME OF APPLICANT
NOVARTIS CONSUMER HEALTH, Inc.

DATE OF SUBMISSION
October 27, 1998

TELEPHONE NO. *(Include Area Code)*
908-598-7816

FACSIMILE (FAX) Number *(Include Area Code)*
908-273-2869

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*
560 Morris Ave.
Summit, NJ 07901-1312

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 20-980

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*
Terbinafine hydrochloride Cream, 1%

PROPRIETARY NAME *(trade name)* IF ANY
not available

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
terbinafine hydrochloride

CODE NAME *(If any)*

DOSAGE FORM:
cream

STRENGTHS:
1%

ROUTE OF ADMINISTRATION:
topical

(PROPOSED) INDICATION(S) FOR USE:
tinea corporis (ringworm), tinea pedis (athlete's foot), tinea cruris (jock itch) and

APPLICATION INFORMATION

APPLICATION TYPE (check one)
☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

REASON FOR SUBMISSION
Protocol for Label Comprehension Study

PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

NDA # 20-192

This application contains the following items: *(Check all that apply)*

	1. Index
	2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Clinical Microbioblogy (e.g. 21 CFR 314.50 (d) (4))
	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
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	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. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
X	19. OTHER (Specify) Protocol for Label Comprehension Study

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80,314.81, 600.80 and 600.81.
7. 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.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Christine Babiuk	Christine Babiuk, PhD Associate Director, Regulatory Affairs	10/27/98

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
Novartis Consumer Health, Inc. 560 Morris Ave., Summit, NJ 07901-1312	(908) 598-7816

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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Please **DO NOT RETURN** this form to this address.

FORM FDA 356h (7/97)

Christine Babiuk, Ph.D.
Associate Director, R.A.

Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, NJ 07901-1312

Tel 908 598 7816
Fax 908 273 2869

NOVARTIS

November 24, 1998

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, MD 20857

NDA 20-980
Terbinafine Hydrochloride Cream, 1%

Rx-to-OTC Switch NDA: Amendment to a Pending Application

Dear Dr. Wilkin:

Reference is made to our telephone conference with the Divisions of Dermatologic and Dental Drug Products and Over-the-Counter Drug Products on October 1, 1998. At that time, we agreed to conduct a label comprehension study using a bifurcated label to test the consumer's ability to treat fungal infections of the foot for the appropriate length of time depending on interdigital or plantar infection. Attached is the study report for bifurcated label comprehension, as well as draft labeling for all packaging components and tube sizes reflecting the inclusion of the moccasin indication. Revised labeling for the jock itch product with new graphics is also included.

The respondents in the label comprehension survey included people who had suffered from plantar or interdigital tinea pedis, random controls, and people with sub-optimal reading ability (eighth grade or-less). The results of the study show that after reading both the carton label and the educational brochure, consumers, in excess of 67% for all populations surveyed, know for how long to apply the cream depending on the location of the fungal infection on the foot.

Novartis Consumer Health, Inc. is confident that the consumer can treat him- or herself appropriately after reading just the carton. The benefit of differentiating interdigital from plantar tinea pedis is that interdigital disease will have a recommended therapy of one week, which should lead to increased compliance, compared to products requiring four weeks of treatment, and resolution of the infection. By differentiating plantar tinea pedis, additional emphasis can be given to the need to treat this form of the disease for a longer period. Therefore, we are proposing that the format of the carton label tested in the label comprehension study be employed in marketing the product.

Please contact the undersigned with any comments or questions concerning the label comprehension study or the proposed labeling being submitted.

Sincerely,

Christine Babiuk

Christine Babiuk, PhD
Associate Director, Regulatory Affairs
Novartis Consumer Health, Inc.

Attachment
Submitted in duplicate
cc: Frank Cross cover letter by facsimile (301-827-2091) and six (6) desk copies

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT
Novartis Consumer Health, Inc.

DATE OF SUBMISSION
November 24, 1998

TELEPHONE NO. *(Include Area Code)*
908-598-7816

FACSIMILE (FAX) Number *(Include Area Code)*
908-273-2869

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*
560 Morris Avenue
Summit, NJ 07901-1312

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 20-980

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*
Terbinafine hydrochloride Cream, 1%

PROPRIETARY NAME *(Trade name)* IF ANY
not available

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
terbinafine hydrochloride

CODE NAME *(If any)*

DOSAGE FORM:
cream

STRENGTHS:
1%

ROUTE OF ADMINISTRATION:
topical

(PROPOSED) INDICATION(S) FOR USE:
tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm)

APPLICATION INFORMATION

APPLICATION TYPE (check one)
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☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
Results of label comprehension study & proposed labeling

PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED one

THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

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CERTIFICATION

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2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80,314.81, 600.80 and 600.81.
7. 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.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Christine Babiuk	Christine Babiuk, PhD Associate Director, Regulatory Affairs	11/24/98

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
Novartis Consumer Health, Inc. 560 Morris Ave., Summit, NJ 07901-1312	(908) 598-7816

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FORM FDA 356h (7/97)

NOVARTIS

Stephenie Barba
Executive Director

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

Tel 973 781 7548
Fax 973 781 6325

March 27, 1998

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. 20-980
Terbinafine Hydrochloride
Cream, 1%

RX-TO-OTC SWITCH NDA

Dear Dr. Wilkin:

In accordance with 21 CFR §314.50, Novartis Pharmaceuticals Corporation herewith submits a New Drug Application for sale without prescription of terbinafine hydrochloride (HCl) cream, 1%. This application will incorporate by reference NDA 20-192 for Lamisil® Cream, 1%, approved December 30, 1992, for chemistry, nonclinical pharmacology, and clinical microbiology information not submitted in this application.

The proposed labeling for the over-the-counter (OTC) terbinafine HCl cream, 1%, will be different from the prescription label in the following ways. First, the indications for treatment will be interdigital tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm). The plantar tinea pedis (moccasin type) indication currently approved for Lamisil® Cream, 1%, will be maintained under prescription status. Second, the label will state that the cream is to be applied for a duration of one week, twice daily for athlete's foot and once daily for jock itch and ringworm. Clinical studies conducted post-approval under NDA 20-192 are being submitted in this application to support the change in the dosing regimen for the proposed OTC product.

Terbinafine has been shown to be both efficacious and safe. Terbinafine HCl cream, 1%, is marketed by prescription worldwide in 82 countries. It is also available OTC with and without the intervention of a pharmacist in seven countries. More than 32 million tubes have been sold worldwide from 1992 through 1996. Assessment of safety data bases, as well as examination of adverse events recorded during the conduct of clinical trials, have demonstrated that the risk of serious medical effects from exposure to terbinafine appears to be very low and of no significant clinical consequence.

You will note during the review of this NDA that Novartis Consumer Health did not conduct an OTC usage study or label comprehension study. Based on our knowledge of the absence of any safety and efficacy issues associated with the use of terbinafine HCl cream, 1%, and the consumer's familiarity both with the above mentioned disease states as well as the numerous treatment options currently available over the counter, we determined that an OTC usage study would not be necessary. Further support of this conclusion is the shorter duration of treatment required with terbinafine HCl cream, 1%, which is expected to result in better compliance with the treatment regimen. Finally symptom recognition and appropriate usage of the OTC terbinafine HCl cream is discussed in an educational package insert, rendering a label comprehension study not necessary in our assessment.

When approved for switch, terbinafine hydrochloride would not be the first in a class of prescription topical antifungal products to achieve OTC marketing status. Based on the existing precedent of safety and efficacy associated with the use of topical antifungals to treat dermatophyte infections such as athlete's foot, jock itch, and ringworm, we do not see the need to present this switch at an Advisory Committee Meeting. However, in the interest of being prepared for such a meeting, we would welcome the opportunity to discuss this with you at the earliest possible date.

Please address any questions or comments regarding this application to:

Christine Babiuk, Ph.D.
Associate Director, Regulatory Affairs
Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, New Jersey 07901-1312

Tel: (908) 598-7816

Sincerely,

Stephenie Barba

Stephenie Barba
Executive Director, Regulatory Affairs
Novartis Pharmaceuticals Corporation

Attachments
Submitted in Duplicate
cc: Division of OTC Drug Products (in duplicate)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on last page.

FOR FDA USE ONLY

APPLICATION NUMBER
20-980

APPLICANT INFORMATION

NAME OF APPLICANT
NOVARTIS PHARMACEUTICALS CORPORATION

DATE OF SUBMISSION
3/27/98

TELEPHONE NO. *(Include Area Code)*
(973)781-7548

FACSIMILE (FAX) Number *(Include Area Code)*
(973)781-6325

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:
59 Route 10
East Hanover, N.J. 07936

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*
TERBINAFINE HYDROCHLORIDE CREAM, 1%

PROPRIETARY NAME *(trade name)* IF ANY
NOT AVAILABLE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
TERBINAFINE HYDROCHLORIDE

CODE NAME *(If any)*

DOSAGE FORM:
CREAM

STRENGTHS:
1%

ROUTE OF ADMINISTRATION:
TOPICAL

(PROPOSED) INDICATION(S) FOR USE: INTERDIGITAL TINEA PEDIS (ATHLETE'S FOOT), TINEA CRURIS (JOCK ITCH) AND TINEA CORPORIS (RINGWORM)

APPLICATION INFORMATION

APPLICATION TYPE (check one)
☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

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IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug
Holder of Approved Application

TYPE OF SUBMISSION (check one)
☒ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
APPROVAL OF NON-PRESCRIPTION STATUS IS BEING SOUGHT

PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 37

THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

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NDA # 20-192 20-749 20-539 IND #

FORM FDA 356h (4/97)

EF

Christine Babiuk, Ph. D.
Associate Director, R.A.

Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, NJ 07901-1312

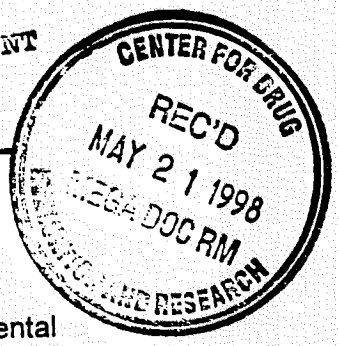
Main Number: 908-598-7600
Fax: 908-273-2869

NOVARTIS

BM

ORIG AMENDMENT

ORIGINAL



May 19, 1998

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 #20-980
Terbinafine Hydrochloride
Cream, 1%

Amendment to a Pending Application

SAS Datasets for Clinical Studies

Dear Dr. Wilkin:

Per the request of the Division of Dermatologic and Dental Drug Products, Novartis Consumer Health, Inc. herewith submits electronic data and corresponding code book documentation for the six terbinafine hydrochloride cream, 1%, clinical studies, 2-1, 2-2, 2508-01, SF0040, 3-1 and 3-2, which had been conducted under NDA 20-192. The corresponding information for study SF2003 will not be available until June.

Information on procedures employed to prepare the data files are presented in Sections I and II.1, entitled "Introduction" and "How Data Files are Prepared", respectively. Because the files are not very large, a SAS transport format was used rather than the previously discussed PKZIP.

Should additional information be required, please contact the undersigned at 908-598-7816.

Sincerely,

Christine Babiuk

Christine Babiuk, Ph.D.
Associate Director, Regulatory Affairs
Novartis Consumer Health, Inc.

Attachments:
Submitted in Duplicate
Desk Copies: Dr. Aurecchia, Dr. Vaughan
cc: cover letter by FAX (301-827-2091) to Frank Cross, CSO Derm. Division

Christine Babiuk, Ph. D.
Associate Director, R.A.

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Tel 908 598 7816
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ORIG AMENDMENT

DUPLICATE

May 27, 1998

Jonathan Wilkin, MD
Director
Division of Dermatological 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, MD 20857

NDA No. 20-980
Terbinafine Hydrochloride Cream, 1%

Amendment to a Pending Application:
GCP Statements

Dear Dr. Wilkin:

Reference is made to the Novartis Consumer Health, Inc. pending New Drug Application for sale without prescription of terbinafine hydrochloride cream, 1%, and to a conversation between the undersigned and Mr. Frank Cross of the FDA on April 30, 1998. During this conversation, Mr. Cross requested that signed GCP statements for each of the studies filed with the NDA be submitted to the FDA by May 29, 1998. We are now officially submitting this documentation to the Division.

This submission includes nine (9) signed GCP statements for five (5) US studies (2-1, 2-2, 2508-01, 3-1 and 3-2) and for four (4) UK studies (SF0040, SF0029, SF2030 and SF2003).

If you have questions or comments concerning this submission, please contact me at 908-598-7816.

Sincerely,

Christine Babiuk

Christine Babiuk, PhD
Associate Director, Regulatory Affairs

Attachments
Submitted in Duplicate
cc: Frank Cross by facsimile (301-827-2091)