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

ORIGINAL

COPY 1

NEW CORRESP

October 15, 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: Notification of Trade Name Selection

Dear Dr. Wilkin:

Reference is made to several discussions with Commander Frank Cross over the last month, and during the October 1, 1998, teleconference with the FDA, concerning the need for Novartis Consumer Health, Inc. to submit the selected trade name for terbinafine hydrochloride cream, 1%, to be marketed over-the-counter, for consideration by the FDA Nomenclature Committee.

The preferred trade name for the OTC terbinafine hydrochloride cream, 1%, is LAMISIL® AT™ Cream. The back-up trade names are LAMISIL® PF™ Cream, and LAMISIL® ST™ Cream, listed in order of decreasing preference. The "AT" stands for advanced treatment, the "PF" stands for prescription formula, and the "ST" stands for short treatment. The attachment lists the preferred and back-up trade names in an enlarged font, to facilitate review.

NCHI would appreciate a response from FDA regarding the acceptability of our preferred trade name, LAMISIL® AT™ Cream, for the over-the-counter product by

early November 1998. Should this not be possible, or if additional information is required, please contact me at 908-598-7816.

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

NDA # 20-980
Novartis Consumer Health, Inc.
Notification of Trade Name Selection

Trade names for terbinafine hydrochloride cream, 1%, for over-the-counter marketing

Preferred Trade Name:
LAMISIL® AT™ Cream

Back-up Trade Names:
LAMISIL® PF™ Cream
LAMISIL® ST™ Cream

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

Novartis Consumer Health, Inc.
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NOVARTIS

February 16, 1999

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: Request for a Tele-conference re. CMC

Dear Dr. Wilkin:

Reference is made to the Novartis Pharmaceuticals Corporation approved NDA for Lamisil® Cream, 1%, (NDA 20-192) and to NDA 20-980 for the over-the-counter marketing of Lamisil Cream which is pending approval. Reference is also made to the teleconference between FDA, Novartis Pharmaceuticals Corp., and Novartis Consumer Health, Inc., which occurred on April 15, 1998.

Novartis hereby requests a teleconference to discuss a CMC supplement initially planned for submission to NDA 20-192, to cover the change of sealant for the tubes. Based on a February 16, 1999, discussion with Commander Frank Cross, it has been recommended to Novartis that the sealant supplement not be submitted until NDA 20-980 has been approved. Novartis informed Mr. Cross that if we are to delay the submission of this CMC supplement until after the pending approval of NDA 20-980, the supply of old tube sealant would be exhausted, and the potential exists for running out of stock of tubes of Lamisil Cream targeted for the OTC market between August and October 1999.

F. Cross suggested that a teleconference was possible for this week to include Dr. De Camp. Participants on behalf of Novartis Pharmaceuticals CMC Regulatory Affairs would be Mr. Robert Clark and on behalf of Novartis Consumer Health, Inc. Regulatory Affairs would be Cynthia Psaras, Ph.D. and myself. Preferred times for the teleconference would be on Thursday, February 18, from 2 to 4 p.m. or on Friday, February 19, from 9 to 4 p.m.

Please confirm with me the time of the teleconference as soon as possible at 908-598-7816. Thank you for your attention in this matter.

Sincerely,

Christine Babiuk

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

Submitted in duplicate

cc: Frank Cross, by facsimile, 301-827-2091

DUPLICATE

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

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

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NOVARTIS

NEW CORRESP
NC

February 24, 1999

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: Correspondence

Dear Dr. Wilkin:

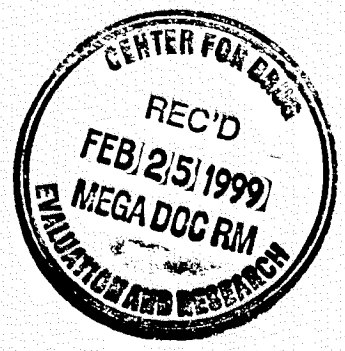
Reference is made to a telephone request from Commander Frank Cross regarding Novartis Consumer Health, Inc. correspondence pertaining to the terbinafine hydrochloride cream, 1%, Rx-to-OTC switch NDA 20-980, which had not officially been submitted to the NDA. In order to comply with the above request, please find enclosed photocopies of two letters written to the Division of Over-the-Counter Drug Products by Dr. Mark Gelbert and Mr. Russ Jones, dated January 21, 1999, and February 18, 1999, respectively.

Should additional information be required, please do not hesitate to contact me at 908-598-7816.

Sincerely,

Christine Babiuk

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



Submitted in duplicate

cc: Frank Cross, by facsimile, 301-827-2091

Mark Gelbert. PhD. JD
Vice President
Scientific Affairs

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

Tel 908 598 7825
Fax 908 273 3676

NOVARTIS

January 21, 1999

Debra Bowen, M.D., Deputy Director
Food & Drug Administration
Office of Drug Evaluation V., HFD-105
9201 Corporate Boulevard
Rockville, MD 20850

Re: Lamisil Cream Rx-OTC Switch – NDA #20-980

Dear Debra,

It's unfortunate we needed to postpone the Quarterly Dialogue meeting this week. I'm sure it will be rescheduled shortly.

I'd like to speak with you on the following switch subject, but thought it would be helpful if I provide you with some background first. I will schedule a call with your assistant.

As you are aware, we are fast approaching the PDUFA date for our switch application for Lamisil cream (March 30, 1998). The review appears to be going well, although we are running up against an issue preparing for launch (assuming approval) for which your support on labeling would be helpful.

Athlete's Foot products are considered by the retail trade to be seasonal. Peak consumer purchases run from June through August. Thus, the retail trade requires product shipments prior to June. We have met with top National retailers (e.g. Walmart, Walgreen's) and they have expressed reluctance to order product beyond the season, suggesting they would wait until Spring 2000 to fully support orders for the product.

The component parts for packaging Lamisil cream, specifically printed (labeled) tubes and cartons have extremely long lead times. For us to have any chance to ship product by late May, we need to order tubes in early February and cartons in late February and begin production in mid-March. The total costs to Novartis if we produce at risk and then have to destroy the product is over I can certainly provide you with more details on this if you are interested.

Our risks in trying to meet our trade dates would be greatly minimized if we could get some assurance that proposed tube and carton labeling is adequate. We were as conservative as possible in drafting the proposed labeling, following FDA guidelines and using other current antifungals as reference.

I know that the FDA cannot assure us that there will be no changes to the proposed tube and carton labels. What I hope we can discuss is that if the changes suggested by FDA do not have a material impact on the safe and effective use of the product, we can make the changes immediately after receiving them while shipping what has been produced based on our submission. We have tested the label among consumers and the results demonstrate that the label is comprehended by nearly 90% of respondents, specifically with regard to dosing directions. Sample labels for cartons and tubes are attached.

Of course, on the more positive side, if we could receive FDA changes to our proposed labeling prior to February 5, we could incorporate the changes and launch with FDA reviewed labeling.

Debra, this is a perfect example of a specific OTC labeling issue that we've been discussing at our Quarterly Dialogue meetings. We have an opportunity to think through a reasonable solution that works for FDA and industry. I would be happy to use this as a positive example during future public meetings.

I look forward to discussing this with you at your earliest convenience. I will set up a time through your assistant.

Sincerely,

Mark Gelbert, PhD, JD
Vice President, Scientific Affairs

MG:bk

Russ Jones
Director
Regulatory Affairs

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

Tel (908) 598-7730
Fax (908) 522-1437

NOVARTIS

February 18, 1999

Fax (301) 827-2317

Office of Drug Evaluation V
Division of Over-The-Counter Drug Products, HFD 105
Food and Drug Administration
9201 Corporate Boulevard
Rockville MD 20850

Attention: Ms. Mary Jane Walling
Associate Director of Regulatory Affairs

RE: **NDA 20-980, Terbinafine Hydrochloride Cream, 1%**
Telephone Conference Call of February 17, 1999

Dear Ms. Walling:

As the designated contact person on the subject of yesterday's telephone conference call with yourself and Drs. Bowen and Katz, it was felt it would be beneficial to provide you with a copy of the revised tube labeling. Attached, please find the labeling as it laid out for the smallest retail tube (12 gm) utilizing the term "cures." The layout reflects that provided by the Division on February 16 (also attached).

The revised tube copy is provided both in actual size and an enlarged version. As you will see, some slight modifications to the agency's suggested layout were made in order to insert the requested foot diagrams and to give as large a type point size as possible. Without these modifications, the type size had to be so reduced it challenged legibility. Although I'm sure the faxed version of the actual size label will be difficult to read, the printed copy will be clear with the main body of the text in 4.5 point type.

If I may be of assistance in any way please feel free to contact me directly by phone (908) 598-7730 or by fax (908) 522-1437.

Sincerely,
Novartis Consumer Health, Inc.

Russ Jones
Director
Regulatory Affairs

RJ:sa

Russ Jones
Director
Regulatory Affairs

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

Tel (908) 598-7730
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NOVARTIS

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DUPLICATE

March 3, 1999

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Products
HFD-540
Center for Drug Evaluation and Research
9201 Corporate Blvd.
Rockville, MD 20850

NDA # 20-980
Terbinafine Hydrochloride
Cream, 1%

Phase IV Commitment
Label Comprehension Study

Dear Dr. Wilkin:

Reference is made to the facsimile sent to Novartis Consumer Health, Inc. (NCHI) by Commander Frank Cross on March 1, 1999 and the telephone conference between NCHI and Dr. Debra Bowen and Dr. Linda Katz from the Division of Over-the-Counter Drug Products on February 17, 1999. NCHI commits to conduct a Phase IV label comprehension study to test consumers' comprehension of the terms "cures," "cures most," and "treats," or other such terminology that might be used for Indications/Uses in all labeling for over-the-counter Lamisil® Cream, 1%, (NDA 20-980) products.

Please contact the undersigned with any questions or comments at 908-598-7730.

Sincerely,

Russ Jones
Director,
Regulatory Affairs

Submitted in duplicate

cc: Frank Cross, by facsimile, 301-827-2091

HFD-540 Cross

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-980

Novartis Pharmaceuticals Corporation
Attention: Stephenie Barba
Executive Director, Regulatory Affairs
59 Route 10
East Hanover, NJ 07936

APR 9 1998

Dear Ms. Barba:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Lamisil (terbinafine Hcl cream) Cream, 1%

Therapeutic Classification: Standard

Date of Application: March 27, 1998

Date of Receipt: March 30, 1998

Our Reference Number: 20-980

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 29, 1998 in accordance with 21 CFR 314.101(a).

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

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours.

/S/

for Mary Jean Kozma-Fornaro
Supervisory, Project Management Staff
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-980
HFD-540/Div. Files
HFD-540/CSO/F.H.Cross
HFD-540/MOTL/Walker
CHTL/Decamp
PHTL/Jacobs

DISTRICT OFFICE

FT: smc/4/8/98

ACKNOWLEDGEMENT (AC)

FEB - 8 '99