DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021124/S-009 **SUPPLEMENT APPROVAL**

Novartis Consumer Health, Inc.
Attention: Karen Costa-Strachan, Ph.D.
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Dr. Costa-Strachan:

Please refer to your supplemental new drug application dated August 12, 2009, received August 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lamisil (1% terbinafine hydrochloride) solution.

We acknowledge receipt of your submissions dated November 9, and 13, 2009, and February 2, 2010.

This "Prior Approval" supplemental new drug application provides for the addition of the "Relieves itching, burning, cracking and scaling," "Clinically proven to cure most athlete's foot between the toes," "The only one week (twice a day) athlete's foot spray," and "Full prescription strength" statements, and a dermatophyte character to the Principal Display Panel for Lamisil AT Spray for athlete's foot.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (Lamisil AT Spray for athlete's foot 125-mL immediate container bottle label submitted February 2, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021124/S-009**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21124	SUPPL-9	NOVARTIS CONSUMER HEALTH INC	LAMISIL AT SMART PUMP/SOLUTION (TERBINAF

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
02/12/2010