DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-124/S-008

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

Dear Dr. Strachan:

Please refer to your supplemental new drug application dated December 17, 2008, received December 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil AT (1% terbinafine hydrochloride) solution.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 125 mL canister and associated labels for Lamisil AT Continuous Spray. The 125 mL canister utilizes the same container closure system as the previously approved 40 mL canister.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the 125-mL Lamisil AT Continuous Spray for athlete's foot and the 125-mL Lamisil AT Continuous Spray for jock itch immediate container labels submitted on December 17, 2008.

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Neel Patel, Regulatory Project Manager, at 301-796-0970.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

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