DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-124/S-007

Novartis Consumer Health, Inc.
Attention: Francis P. Barbone, Ph.D.
Global Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Dr. Barbone:

Please refer to your supplemental new drug application dated November 5, 2007, received November 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil AT (1% terbinafine hydrochloride) solution.

We acknowledge receipt of your submission dated June 11, 2008.

Your submission of June 11, 2008 constituted a complete response to our March 6, 2008 action letter.

This supplemental new drug application provides for a new continuous spray container closure system for Lamisil AT and a new trade name, Lamisil AT Continuous Spray, for this product configuration.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the 40-mL Lamisil AT Continuous Spray for athlete's foot and the 40-mL Lamisil AT Continuous Spray for jock itch immediate container and carton labels submitted on March 4, 2008.

We remind you to remove the flag "New" from the principal display panel six months after introduction into the marketplace.

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

Please submit one market package of the drug product when it is available.

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

7/25/2008 11:00:38 AM