DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-980/S-005

Novartis Consumer Health, Inc.
Attention: Vanessa Yizar
Manager, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Ms. Yizar:

Please refer to your supplemental new drug application dated January 26, 2007, received January 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil AT (1 % terbinafine hydrochloride) cream.

We acknowledge receipt of your submissions dated June 7, and July 5, 2007.

This supplemental new drug application provides for the addition of a new Lamisil AT package directed toward treating athlete's foot in women.

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 final printed labeling (FPL) for the 24-gram women's Athlete's Foot cream immediate container and carton labels submitted on July 5, 2007.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 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, MD
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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