DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-958

Novartis Consumer Healthcare
Attention: Donna Coughlin
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Ms. Coughlin:

Please refer to your new drug application (NDA) dated September 29, 2005 received September 30, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil AT (1 % terbinafine) Gel.

We acknowledge receipt of your submissions dated October 28, and November 28, 2005, and February 9, March 28, April 20, May 26, June 6 and 29, and July 20, 2006.

This new drug application provides for the use of Lamisil AT (1 % terbinafine) Gel for treatment of interdigital-type tinea pedis (athlete's foot), tinea cruris (jock itch), and tinea corporis (ringworm).

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (Lamisil AT Gel for athlete's foot and Lamisil AT Gel for jock itch 6- and 12-gram immediate container and carton labels submitted July 20, 2006), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL for all stock keeping units according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-958**." Approval of this submission by FDA is not required before the labeling is used.

(b)(4)

If you choose to place the flag "New" on the principal display panel, we remind you that it must be removed six months after introduction into the OTC 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, HFD-410
FDA
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 reporting 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}

Susan Walker, M.D
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Susan Walker
7/24/2006 05:06:57 PM

Andrea Segal
7/24/2006 05:37:21 PM