DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-307/S-004

Schering-Plough HealthCare Products
Attention: Doreen Frank
Associate Director, Regulatory Affairs
556 Morris Ave
Summit, NJ 07901-1330

Dear Ms. Frank:

Please refer to your supplemental new drug application dated August 11, 2005, received August 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrimin Ultra (1% butenafine HCl) Cream.

We acknowledge receipt of your submissions dated November 4, and November 7, 2005, and January 20, 2006.

This supplemental new drug application proposes revised labeling on the Principal Display Panel.

We have completed our review of this application, as amended. This application 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 submitted labeling (immediate container labels for the athlete's foot SKU submitted November 4, 2005 (24 g tube) and November 7, 2005 (12 g tube), carton labels for the athlete's foot SKU submitted August 11, 2005, and immediate container and carton labels for the jock itch SKU submitted January 20, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

At the present time, you can continue to include the "Full Prescription Strength" language on the principal display panel. We will provide guidance on this language and placement in the labeling of over-the-counter drug products in the future.

In your submission dated August 11, 2005, you note that "no available evidence suggests that consumers will confuse Lotrimin Ultra with butenafine prescription products or otherwise select Lotrimin Ultra to self treat for prescription uses due to the "Full Prescription Strength" statement." This suggests that you are aware of data that has evaluated the use of the "Full Prescription Strength" or similar language on over-the-counter (OTC) products, and it does not influence consumers or patients to use an OTC product for prescription indications. We request that you submit any consumer behavior data, which you have conducted or have contracted for on behalf of your company, assessing the "Full Prescription Strength" or similar language. This would include information from surveys, focus testing, label comprehension or other studies. These studies may have been conducted for

general consumer testing unrelated to a specific product or related to Lotrimin or other products marketed by your company. Additionally, we request that you submit information on how you have used the "Full Prescription Strength" language in any advertising for the Lotrimin products or other products marketed by your company. Please provide this information within 60 days or notify us if you believe you will need additional time.

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 supplement NDA 21-307/S-004**." Approval of this submission by FDA is not required before the labeling is used.

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

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 Leah Christl, Regulatory Project Manager, at (301) 301-796-0869.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Office of New Drugs
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/

Charles Ganley
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