DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021307/S-014 **SUPPLEMENT APPROVAL**

Merck Consumer Care, Inc.
Attention: Sangeeta Patel
Associate Director, CMC Regulatory Affairs
Mail Stop: S-4-2-2190B
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated February 17, 2014, received February 19, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lotrimin Ultra (butenafine hydrochloride) cream, 1%.

We acknowledge receipt of your amendments dated May 30 and July 17, 2014.

This supplemental application proposes to replace the excipient diethanolamine (DEA) with trolamine (b) (4) to comply with California's Proposition 65 which listed diethanolamine as a potential carcinogen.

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.

## LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling submitted on February 17, 2014 for the following:

- 12 g carton and tube Lotrimin Ultra for Athlete's Foot (AF)
- 12 g carton and tube Lotrimin Ultra for Jock Itch (JI)

In addition, labeling for all the affected SKUs must be submitted and include:

- 12 g carton and tube Lotrimin Ultra for Athlete's Foot (AF)
- 15 g carton and tube Lotrimin Ultra for Athlete's Foot (AF)
- 24 g carton and tube Lotrimin Ultra for Athlete's Foot (AF)
- 30 g carton and tube Lotrimin Ultra for Athlete's Foot (AF)
- 12 g carton and tube Lotrimin Ultra for Jock Itch (JI)
- 15 g carton and tube Lotrimin Ultra for Jock Itch (JI)

Submit FPL in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021307/S-014**". Approval of this submission by FDA is not required before the labeling is used.

**DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

**REPORTING REQUIREMENTS**

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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

Sincerely,

*{See appended electronic signature page}*

Theresa Michele, M.D.
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

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

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/s/

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THERESA M MICHELE
12/17/2014