DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021307/S-013

SUPPLEMENT APPROVAL

Merck Consumer Care
Attention: Cynthia Andersen
Manager, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Andersen:

Please refer to your Supplemental New Drug Application (sNDA) dated November 9, 2011 and received November 10, 2011 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lotrimin Ultra® (butenafine hydrochloride) cream, 1%.

We acknowledge receipt of your amendment dated April 20, 2012.

This "Prior Approval" supplemental new drug application proposes to revise the claim "Full Prescription Strength" to "Prescription Strength" and to enlarge the font and reposition the claim under the proprietary name on the fifth panel and on the principal display panel (PDP) of the carton label for Lotrimin Ultra® for Athlete's Foot and Lotrimin Ultra® for Jock Itch.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling submitted April 20, 2012, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- Lotrimin Ultra® for Athlete's Foot 12-gram carton label
  - Representative of 12-, 15-, 24-, and 30-gram carton labels

- Lotrimin Ultra® for Jock Itch. 12-gram carton label
  - Representative of 12- and 15-gram carton labels

Even though no revisions were made to the immediate container labels as part of this supplement, submit immediate container labels as part of the FPL in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

FPL must be submitted for all representative count sizes. Representative labeling will not be acceptable in the FPL submission.

The final printed labeling 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-013**." 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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures: Carton Labeling

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
05/02/2012