DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021307/S-015 **SUPPLEMENT APPROVAL**

Bayer HealthCare LLC
Attention: Yake Yu
Senior Manager, Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Mr. Yu:

Please refer to your Supplemental New Drug Application (sNDA) dated June 11, 2015, received June 12, 2015 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lotrimin Ultra® (butenafine hydrochloride) cream, 1%.

This "Prior Approval" sNDA provides for the following labeling revisions affecting SKUs labeled for use in jock itch (12, 15g) and for athlete's foot (12, 15, 30g):

- updates the trademark statement, copyright notice, and distributor's address to reflect the application ownership by Bayer HealthCare LLC on all SKUs
- adds claim statement *1 Week Treatment Option For Athlete's Foot See Directions* only to Lotrimin Ultra Athlete's Foot SKUs' carton labeling
- adds a $2 instant redeemable coupon (IRC) front and back label as a sticker placed only on Lotrimin Ultra Athlete's Foot 30 g carton labeling
- adds bonus language *Bonus 15g for the price of 12g 25% more* to both Lotrimin Ultra Athlete's Foot and Lotrimin Ultra Jock Itch, 15g carton labeling

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 June 11, 2015, and October 7, 2015 as follows:

June 11, 2015 submission

- 12 g, 15 g, 30 g immediate container (tube) Lotrimin Ultra for athlete's foot
- 12 g, 15 g immediate container (tube) Lotrimin Ultra for jock itch
- 12 g, 15 g outer container (carton) Lotrimin Ultra for jock itch
- $2IRC to be applied to 30 g outer container (carton) Lotrimin Ultra for athlete's foot
- $2IRC on a 30 g carton for Lotrimin Ultra for Athlete's Foot – just for coupon placement

October 7, 2015 submission

- 12 g, 15 g, 30 g outer container (carton) Lotrimin Ultra for athlete's foot

We remind you that the 30 g athlete's foot product carton labeling submitted October 7, 2015, to be marketed with the $2 IRC will place the IRC in the identical location as was shown on the 30 g carton labeling with affixed IRC example image submitted June 11, 2015.

Submit 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-015"**
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, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and IRC Labeling

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

/s/

THERESA M MICHELE
12/18/2015