



NDA 021124/S-013

SUPPLEMENT APPROVAL

Novartis Consumer Health, Inc.
Attention: Iris Ampofo-Barnes
Regulatory Project Manager
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Ms. Ampofo-Barnes:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on May 14, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lamisil^{AT}® (terbinafine hydrochloride) solution, 1%.

We acknowledge receipt of your amendments dated October 2 and 25, 2013.

This “Changes Being Effected” supplemental new drug application provides for the addition of a pressure warning statement in the **Drug Facts** label (*Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 deg. F*), and minor editorial changes.

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.

In addition, we remind you of your October 25, 2013 submission in which you commit to revise

(b) (4)

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 on May 14, 2013, for the following:

- 125 mL, Immediate container label for Lamisil^{AT} Spray for Athlete’s foot
- 125 mL, Immediate container label for Lamisil^{AT} Spray for Jock itch

Submit in “Drug Facts” format (21 CFR 201.66), where applicable.

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 021124/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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

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:

Immediate container 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
11/13/2013