



NDA 204153/S-002

**SUPPLEMENT APPROVAL**

Medicis Pharmaceutical Corporation  
Attention: Sean Humphrey  
Sr. Manager, Regulatory Affairs  
1330 Redwood Way, Suite C  
Petaluma, CA 94954

Dear Mr. Humphrey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 12, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUZU (luliconazole) cream, 1%.

We also refer to our approval letter dated February 8, 2017 which contained the following error: language was incorrectly included for fulfillment of Postmarketing Commitment 2101-3 on Page 2 of the letter. We note that PMC 2101-3 was already fulfilled per the FDA letter dated May 17, 2016.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 8, 2017, the date of the original approval letter.

This Prior Approval supplemental new drug application provides updates to section 8 of the prescribing information to conform to the Pregnancy and Lactation Labeling Rule (PLLR), and proposed updates to section 12.3 to include information about CYP2C19 from a postmarketing study.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text which includes the minor editorial revisions listed below.

The italics were removed from the words “in vitro” and “in vivo” wherever they appeared in the labeling.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert) with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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 Pinky Patel, Regulatory Health Project Manager, at (301) 796-7475

Sincerely,

*{See appended electronic signature page}*

Kendall A. Marcus, MD  
Director  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of 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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KENDALL A MARCUS  
02/08/2017