



NDA 18533/S-041

**SUPPLEMENT APPROVAL**

Janssen Research & Development, LLC  
Attention: Melissa L. Gannon  
Director, Global Regulatory Affairs  
920 Route 202 South  
P.O. Box 300  
Raritan, NJ 08869-0602

Dear Ms. Gannon:

Please refer to your Supplemental New Drug Application (sNDA) dated August 30, 2013, received August 30, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nizoral (ketoconazole) Tablet, 200 mg.

We acknowledge receipt of your amendment dated December 19, 2013.

This "Prior Approval" supplemental new drug application provides for revisions to the following sections of labeling:

- **BOXED WARNING**
- **CLINICAL PHARMACOLOGY** Section, **Pharmacokinetics** subsection
- **WARNINGS** Section, **QT Prolongation and Drug Interaction Leading to QT Prolongation** subsection
- **PRECAUTIONS** Section, **Drug Interactions** subsection
- **Medication Guide**

**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.

**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 Medication

Guide), 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 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).

### **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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, M.D., M.P.H.  
Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
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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SUMATHI NAMBIAR  
02/25/2014