



NDA 022003/S-025  
NDA 205053/S-009  
NDA 205596/S-008

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.  
Attention: Neetesh Bhandari, B.V.Sc., Ph.D., DABT  
Director, Global Regulatory Affairs  
351 North Sumneytown Pike  
P.O. Box 1000, UG 2CD-48  
North Wales, PA 19454

Dear Dr. Bhandari:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 26, 2018, received July 26, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product	NDA #	Supplement #
Noxafil (posaconazole) oral suspension, 40 mg/mL	022003	S-025
Noxafil (posaconazole) delayed-release tablets, 100 mg	205053	S-009
Noxafil (posaconazole) injection, 18 mg/mL	205596	S-008

These Prior Approval supplemental new drug applications provide for revised language regarding electrolyte disturbance in the **WARNINGS AND PRECAUTIONS (5)** section, **Arrhythmias and QT Prolongation (5.2)** subsection, and in the **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.3)** subsection of the prescribing information (PI). Additionally, a new subsection, **Electrolyte Disturbances (5.3)**, has been added to the **WARNINGS AND PRECAUTIONS (5)** section, and the term pseudoaldosteronism has been added to the **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.3)** subsection. The **HIGHLIGHTS OF PRESCRIBING INFORMATION, RECENT MAJOR CHANGES**, and **FULL PRESCRIBING INFORMATION: CONTENTS** have also been updated to reflect the changes made to the PI and minor editorial revisions have been made throughout the labeling.

## **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## **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 Prescribing Information) 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 these NDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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If you have any questions, call Alison Rodgers, Regulatory Project Manager, at 301-796-0797.

Sincerely,

*{See appended electronic signature page}*

Joseph G. Toerner, MD, MPH  
Deputy Director for Safety  
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. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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JOSEPH G TOERNER  
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