DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022003/S-024
NDA 205053/S-008
NDA 205596/S-007

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 June 20, 2018, received June 20, 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	024
Noxafil (posaconazole) delayed-release tablets, 100 mg	205053	008
Noxafil (posaconazole) injection, 18 mg/mL	205596	007

These Prior Approval supplemental new drug applications provide for revisions to the Noxafil prescribing information (PI) to be in compliance with the FDA Pregnancy and Lactation Labeling Rule (PLLR). Specifically, revisions have been made to the **USE IN SPECIFIC POPULATIONS (8)** section, **Pregnancy (8.1)** and **Lactation (8.2)** subsections. In addition, in the **ADVERSE REACTIONS (6)** section, the **Serious and Otherwise Important Adverse Reactions (6.1)** subsection was removed and the **Clinical Trials Experience (6.2)** and **Postmarketing Experience (6.3)** subsections renumbered. The **CLINICAL PHARMACOLOGY (12)** section, **Microbiology (12.4)** subsection was updated in accordance with the final guidance, "*Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs.*" Additionally, minor editorial revisions have been made throughout the PI.

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.

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).

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

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Prescribing Information

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.

/s/

DMITRI IARIKOV
03/11/2019 11:52:45 AM