NDA 022003/S-026
NDA 205053/S-010
NDA 205596/S-010

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Attention: Heather Tiscia
Director, Global Regulatory Affairs
351 North Sumneytown Pike, P.O. Box 1000
UG 2D-068
North Wales, PA 19454-2505

Dear Ms. Tiscia:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 022003/S-026, Noxafil (posaconazole) oral suspension, 40 mg/mL
NDA 205053/S-010, Noxafil (posaconazole) delayed-release tablets, 100 mg
NDA 205596/S-010, Noxafil (posaconazole) injection, 18 mg/mL

These "Changes Being Effected" supplemental new drug applications provide for a revision to the **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection, to remove the reference to 'see *Adverse Reactions (6.2)*' from Endocrine Disorders, as requested by the Agency in the December 5, 2019 communication. Additionally, these supplements provide for the following changes:

(1) Removal of **RECENT MAJOR CHANGES** from the **HIGHLIGHTS OF PRESCRIBING INFORMATION.**
(2) Revision to the **DOSAGE AND ADMINISTRATION (2)** section, **Dosage, Preparation, Intravenous Line Compatibility, and Administration of Noxafil Injection (2.2)** subsection, regarding discarding any unused portion.
(3) Addition of the package type term "single dose" to the **DOSAGE FORMS AND STRENGTHS (3)** section.
(4) Addition of identifying characteristics of the oral suspension and injection dosage forms to the **DOSAGE FORMS AND STRENGTHS (3)** and the **HOW SUPPLIED/STORAGE AND HANDLING (16)** sections.
(5) Deletion of the manufacturers' addresses from the **PRESCRIBING INFORMATION** and the **Patient Information**.

Additionally, a statement indicating that the drug product is sterile has been added to the injection carton and container labels and editorial revisions have been made throughout the prescribing information.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon 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 FDA.gov.[1] 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling for Noxafil (posaconazole) injection, 18 mg/mL [NDA 205596] that is identical to the enclosed carton and container labeling as soon as it is available, but no more than 30 days after it is printed. Please submit this

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 205596/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Information
- Carton and Container Labeling [NDA 205596 only]

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
09/16/2020 11:56:52 AM