NDA 205053/S-011
NDA 205596/S-013

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
a subsidiary of Merck & Co., Inc.
Attention: Deanne Jackson Rudd, Ph.D.
Director, Global Regulatory Affairs and Clinical Safety
351 North Sumneytown Pike
P.O. Box 1000, UG-2D-068
North Wales, PA 19454-2505

Dear Dr. Rudd:

Please refer to your supplemental new drug applications (sNDAs) dated and received August 19, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Noxafil (posaconazole) delayed-release tablets, 100 mg (NDA 205053/S-011) and Noxafil (posaconazole) injection, 300 mg/16.7 mL (18 mg/mL) (NDA 205596/S-013).

These Prior Approval supplemental new drug applications provide for the use of Noxafil (posaconazole) delayed release tablets, 100 mg and Noxafil (posaconazole) injection, 18 mg/mL for the treatment of invasive aspergillosis in patients 13 years of age and older and provide updates to sections of prescribing information (PI) relevant to the use of Noxafil delayed release tablets and Noxafil (posaconazole) injection for the treatment of Invasive aspergillosis in patients 13 years of age and older.

APPROVAL & LABELING

We have completed our review of these applications. 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 and the Patient Package Insert with the addition of any labeling changes in pending “Changes

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because these drug products for this indication have an orphan drug designation, 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).

[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.

If you have any questions, call Christopher L. Smith, PharmD, Regulatory Project Manager, at (301) 796-4851.

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 Package Insert

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
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