



NDA 22003/S-030

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, UG2D-068
North Wales, PA 19454

Dear Dr. Rudd:

Please refer to your supplemental new drug application (sNDA) dated and received August 19, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Noxafil (posaconazole) oral suspension, 40 mg/mL.

This Prior Approval sNDA provides for revisions to the carton labeling in response to the June 25, 2021, supplement request letter to add that the oral suspension is not substitutable with the PowderMix formulation. The sNDA also provides for annual reportable changes.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELING

Submit final printed carton labeling that is identical to the enclosed carton labeling as soon as it is available, but no more than 30 days after it is printed. Please submit this 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 22003/S-030.**” 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):

- Carton Labeling

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
01/03/2022 10:57:49 AM