DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22003/S-016

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Joanna Pols, PhD
Director, Global Regulatory Affairs
126 E. Lincoln Avenue, P.O. Box 2000
RY34-B188
Rahway, NJ 07065

Dear Dr. Pols:

Please refer to your Supplemental New Drug Application (sNDA) dated February 11, 2015, received February 11, 2015, 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" supplemental new drug application provides for the following changes to the carton and container labeling as requested in our January 12, 2015, letter:

(1) Increased the prominence of the statement of strength and net quantity
(2) Moved the net quantity statement to the top third of the principal display panel; and
(3) Increased the prominence of the statement "each mL contains 40 mg of posaconazole.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge that this submission contains final printed carton and container labels.

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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
07/14/2015