DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22003/S-011 and S-012
NDA 22027/S-002 and S-003

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Barbara Gunther, MA, MBA
Associate Director & Liaison
Worldwide Regulatory Affairs
2015 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Gunther:

Please refer to the following Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Noxafil (posaconazole) Oral Suspension.

NDA/Supplement Number	**Date Supplement Submitted and Received**	**These "Prior Approval Supplements" provide for the following:**
NDA 22003/S-011 NDA 22027 S-002	July 18, 2011	(1) Addition of fosamprenavir as a drug interaction and (2) Deletion of the statement concerning dose adjustment for Ritonavir and Atazanavir from the **DRUG INTERACTIONS** section of the labeling. (3) Minor editorial and format changes.
NDA 22003/S-012 NDA 22027/S-003	September 23, 2011	(1) Clarified and strengthened contraindication for concomitant administration with statins (simvastatin) to include HMG-CoA reductase inhibitors primarily metabolized through CYP3A4. (2) Addition of fever and coughing to the **HIGHLIGHTS** under **ADVERSE REACTIONS**.

Additionally, these supplements provide for the removal of section 12.4, **Activity in Animal Models** subsection, and section 13.2, **Animal Toxicology and/or Pharmacology** from the labeling text and from the **FULL PRESCRIBING INFORMATION** section of the labeling as requested by the Division in an email communication of May 29, 2012.

We also refer to our approval letter dated June 21, 2012, which contained the following error: Text for the Patient Package Insert was not attached.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 21, 2012, the date of the original approval letter.

We acknowledge receipt of your amendments dated February 24, May 3, and June 7, 2012.

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 submitted June 7, 2012 [#56592-POS-SUo-USPI-25, Rev. 6/2012] and May 3, 2012 [#056592-POS-SUo-PPI.9, Rev. 6/2012].

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 package insert, text for the patient package insert), 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 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in these supplements, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling