DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-003/S-008
NDA 22-027/S-001

SUPPLEMENT APPROVAL

Schering Corporation
Attention: Ms. Barbara Line Gunther, MA, MBA
Associate Director & Liaison
Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Gunther:

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

Drug Product Name	**NDA Number**	**Supplement Number**	**Date of Supplement**	**Date of Receipt**
Noxafil® (posaconazole) Oral Suspension, 40 mg/mL	22-003	008	June 12, 2009	June 15, 2009
Noxafil® (posaconazole) Oral Suspension, 40 mg/mL	22-027	001	June 18, 2009	June 19, 2009

We acknowledge receipt of your amendments dated November 25, 2009, and March 5, August 16, September 2, and September 7, 2010.

The March 5, 2010, submission constituted a complete response to our December 4, 2009 action letter.

These Prior Approval supplemental new drug applications provide for revisions to the product labeling in response to our February 24, 2009 letter that outlined the implementation plan for the January 24, 2006, Final Rule titled, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* (Federal Register Vol. 71, No. 15, 3921-3997). Specifically, these sNDAs provide for conversion of the current approved labeling to the format required by the Physician Labeling Rule in accordance with 21 CFR 201.56 and 201.57 and also provide for the following updated information:

- Interaction of posaconazole and HMG-CoA reductase inhibitors metabolized through CYP3A4 in the **DRUG INTERACTIONS** section of the labeling,

- Information on torsades de pointes in the **WARNINGS AND PRECAUTIONS** section and the **ADVERSE REACTIONS** section of the labeling,

- Editorial revisions in Table 8, Table 9, Table 13, and section 7.2 of the labeling, and

- Changes to the patient package insert (PPI) under headings **"What should I tell my doctor before taking NOXAFIL®?", "What are possible side effects of NOXAFIL®?", "Who should not take NOXAFIL®?"** and **"How do I take NOXAFIL®?"**

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 new drug applications for these NDAs, including pending "Changes Being Effected" (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.

LABELING

Submit final printed labeling as soon as it is available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the package insert.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human

Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate these submissions **"Final Printed Labeling for approved NDA 22-003/S-008; NDA 22-027/S-001."** Approval of these submissions by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to these NDAs, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Jacquelyn Smith, M.A., Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures: Package Insert
Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22027	SUPPL-1	SCHERING CORP	4070200 (POSACONAZOLE)
NDA-22003	SUPPL-8	SCHERING CORP	NOXAFIL (POSACONAZOLE)

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/s/

RENATA ALBRECHT
09/08/2010