DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-003

Schering Corporation
Attention: Todd Paporello, Pharm.D., M.B.A.
Associate Director and Liason, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Paporello:

Please refer to your new drug application (NDA) dated December 21, 2005, received December 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noxafil® (posaconazole) Oral Suspension, 40mg/mL.

We acknowledge receipt of your submissions dated:

January 20, 2006	April 21, 2006	June 2, 2006
February 23, 2006	May 8, 2006	June 16, 2006
March 8, 2006	May 9, 2006	June 20, 2006
March 17, 2006	May 11, 2006	June 22, 2006
March 20, 2006	May 16, 2006	August 23, 2006
March 21, 2006	May 22, 2006	August 29, 2006
April 7, 2006	May 23, 2006	September 8, 2006
April 17, 2006	May 26, 2006 (2)	September 15, 2006

This new drug application provides for the use of Noxafil® (posaconazole) Oral Suspension for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with Graft versus Host Disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

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

Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement at this time for patients thirteen to sixteen years

of age. We are deferring submission of your pediatric studies for patients zero months to twelve years of age until September 15, 2011.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for prophylaxis of invasive fungal infections in pediatric patients ages zero months to twelve years of age who are at high risk for developing these infections.

   Final Report Submission: September 15, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment.**"

In addition, we remind you of your postmarketing study commitment, specified in your submissions dated June 22 and August 23, 2006. This commitment is stated below.

2. A post approval study will be conducted among patients receiving antifungal prophylaxis. The study will enroll patients who are at risk for low absorption. Different dosing strategies including the use of therapeutic drug monitoring to increase plasma concentrations will be explored.

   Protocol Submission: by January 2007
   Study Start: by January 2008
   Final Report Submission: by March 2011

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol,**" "**Postmarketing Study Commitment Final Report,**" or "**Postmarketing Study Commitment Correspondence**."

The following are not postmarketing study commitments; however, we request the following information be submitted:

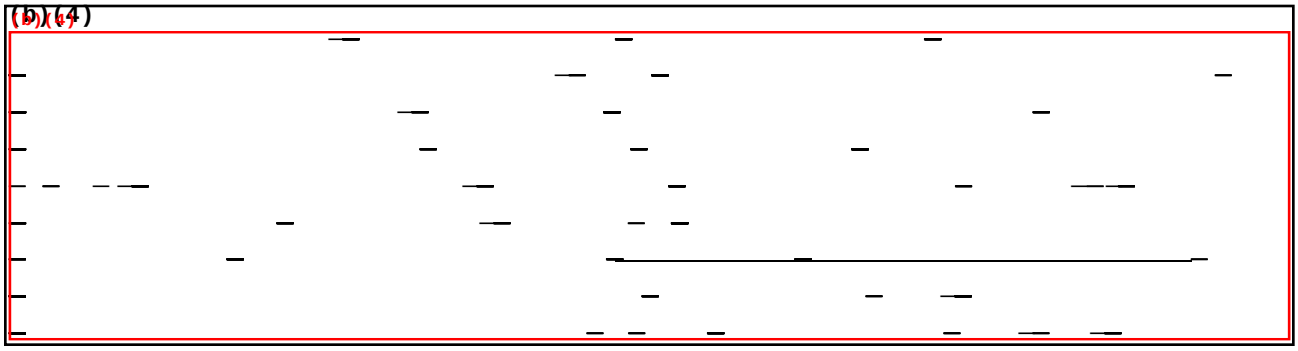
We note your agreement to submit reports 3 and 4, specified in your submissions dated June 20 and August 23, 2006:

3. Detailed reports of thrombotic or microangiopathic events, such as hemolytic uremic syndrome (HUS), thrombotic thrombocytopenic purpura (TTP), pulmonary embolus, etc. will be submitted quarterly for three years.

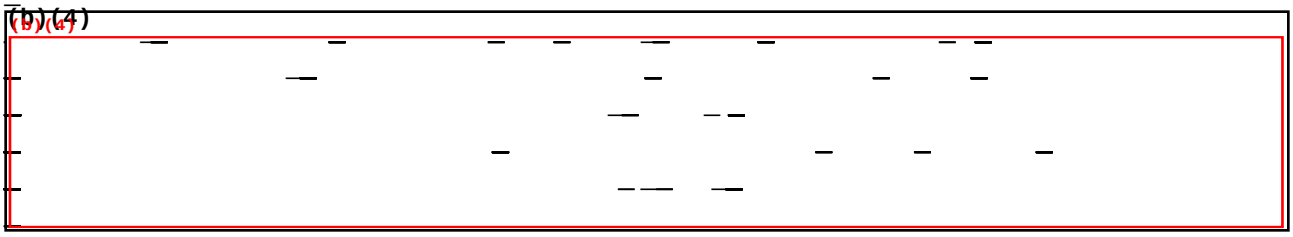
4. Utilization data and indications, when known, will be submitted every six months for three years.

In addition, please note that items (b)(4).

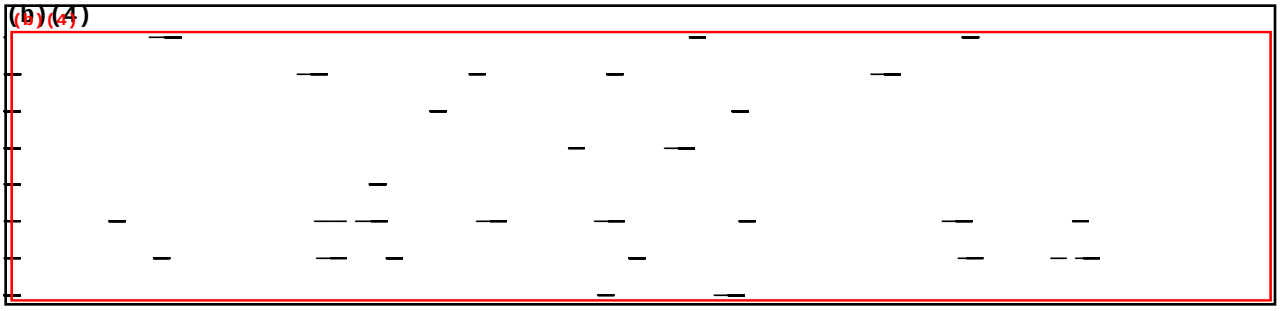
5. (b)(4)



6. (b)(4)



7. (b)(4)



In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics

qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, please call Kristen Miller, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Edward Cox, M.D., M.P.H
Acting Director
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Edward Cox

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