CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-027

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-027

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:

December 20, 2006	April 17, 2006	May 26, 2006 (2)	July 28, 2006
January 20, 2006	April 21, 2006	June 2, 2006	August 1, 2006
February 23, 2006	May 8, 2006	June 16, 2006	August 11, 2006
March 8, 2006	May 9, 2006	June 20, 2006 (2)	August 23, 2006
March 17, 2006	May 11, 2006	June 22, 2006 (2)	October 5, 206
March 20, 2006	May 16, 2006	June 30, 2006	October 16, 2006
March 21, 2006	May 22, 2006	July 14, 2006	October 19, 2006
April 7, 2006	May 23, 2006	July 21, 2006	

This new drug application provides for the use of Noxafil® (posaconazole) Oral Suspension for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole.

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 are deferring submission of your pediatric studies for patients zero months to sixteen years of age until October 20, 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 the treatment of oropharyngeal candidiasis in pediatric patients ages zero months to sixteen years of age.

   Final Report Submission: October 20, 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, 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 this division 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).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original **NDA 22-003** for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the structured product labeling requested above.

If you have any questions, please call Kristen Miller, Pharm.D., Regulatory 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

Enclosure

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

/s/

Renata Albrecht
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