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RESEARCH**

APPLICATION NUMBER:

21-630

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-630

Pfizer Inc., Global Research & Development
Attention: Maureen H. Garvey, Ph.D.
Director, Regulatory Strategy and Registration
Worldwide Regulatory Affairs
50 Pequot Avenue
New London, CT 06320

Dear Dr. Garvey:

Please refer to your new drug application (NDA) dated March 14, 2003, received March 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VFEND[®] (voriconazole) for Oral Suspension.

We acknowledge receipt of your submissions dated:

April 9, 2003	November 25, 2003 (2)
May 14, 2003	December 16, 2003
November 14, 2003 (2)	December 19, 2003
November 24, 2003	

This new drug application provides for the use of VFEND[®] (voriconazole) for Oral Suspension for invasive aspergillosis; esophageal candidiasis; and serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium* spp., including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy.

We have 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted December 19, 2003) and submitted labeling (immediate carton and container labels submitted March 14, 2003). Marketing the product with FPL that is not identical to this approved labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For

administrative purposes, designate this submission **"FPL for approved NDA 21-630."** Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated December 19, 2003. This commitment is listed below.

1. Description of Commitment

Conduct a two-way drug interaction study between voriconazole and oral contraceptives.

Protocol Submission: by March 15, 2004
Study Start: by April 15, 2004
Final Report Submission: by March 15, 2005

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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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).

If you have any questions, call Rebecca Saville, Pharm.D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
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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