DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-464
NDA 21-466

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 applications (NDAs) dated November 17, 2000, received November 17, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VFEND™ (voriconazole) Tablets, NDA 21-464, and VFEND™ (voriconazole for injection) I.V., NDA 21-466.

We acknowledge receipt of your submissions dated May 13, 2003 that constitute a complete response to our December 17, 2001 action letter, as well as your submissions dated July 18, 2002, May 13, 2003, and November 11, 2003.

These new drug applications provide for the use of VFEND™ (voriconazole) Tablets and VFEND™ (voriconazole for injection) I.V. for esophageal candidiasis.

We have completed our review of these applications, as amended. They are 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). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

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 these submissions "**FPL for approved NDA 21-464 and NDA 21-466**." Approval of these submissions by FDA is not required before the labeling is used.

FDA's Pediatric Rule at 21 CFR 314.55 was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, if you do not conduct pediatric clinical trials

as outlined in your Written Request, we encourage you to submit a pediatric plan that describes development of your products in the pediatric population where they may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. We acknowledge your revised Written Request, dated July 3, 2002.

In addition, submit three copies of the introductory promotional materials that you propose to use for this new indication for these products. 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 inserts directly to:

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

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 21-266 and NDA 21-267 for these drug products, not to these NDAs. In the future, do not make submissions to these NDAs except for the final printed labeling requested above.

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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