DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-266/S-007
NDA 21-267/S-007

C.P. Pharmaceuticals International C.V.
c/o Pfizer Inc.
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 supplemental new drug applications dated January 6, 2004, received January 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VFEND® (voriconazole) Tablets, 50 mg and 200 mg and VFEND® I.V. (voriconazole) for Injection.

We acknowledge receipt of your submissions dated January 6, 2004.

These supplemental new drug applications provide for the addition of information regarding VFEND® (voriconazole) for Oral Suspension (NDA 21-630) that was approved on December 19, 2003.

We completed our review of these applications, as amended. These applications 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 submitted January 6, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated **"FPL for approved supplement NDA 21-266/S-007 and NDA 21-267/S-007."** Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HFD-410
FDA
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).

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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