DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-266/S-009
NDA 21-267/S-009
NDA 21-630/S-003

C.P. Pharmaceuticals International C.V.
c/o Pfizer, Inc.
Attn: Maureen H. Garvey, Ph.D.
Senior Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Dr. Garvey:

Please refer to your new drug applications (NDA) dated March 15, 2004, received March 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA	Supplement Number
VFEND® (voriconazole) Tablets, 50 mg and 200 mg	21-266	S-009
VFEND® I.V. (voriconazole) for Injection, 10 mg/mL	21-267	S-009
VFEND® (voriconazole) for Oral Suspension, 45 mg/mL	21-630	S-003

We acknowledge receipt of your submissions dated:

March 15, 2004
April 9, 2004 (2)
April 26, 2004 (2)
May 14, 2004 (2)
May 18, 2004 (2)
July 22, 2004
July 23, 2004
August 13, 2004
September 29, 2004 (2)
September 30, 2004
December 14, 2004
December 17, 2004
December 20, 2004

These supplemental new drug applications provide for the use of VFEND® for candidemia in nonneutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

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 December 20, 2004). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidance documents for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidance documents specify that labeling be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

For administrative purposes, designate these submissions "**FPL for approved supplements NDA 21-266/S-009, NDA 21-267/S-009, and NDA 21-630/S-003**." Approval of these submissions by FDA is not required before the labeling is used.

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 ages 0 to 16 years until December 31, 2010.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies 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 candidemia and invasive candidiasis infections in pediatric patients ages 0 to 16.

   Final Report Submission: December 31, 2010

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

In addition, as required by 21 CFR 314.550, submit three copies of the introductory promotional materials that you propose to use 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 proposed package inserts directly to:

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

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 D. 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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