



NDA 21-266/S-013
NDA 21-267/S-012
NDA 21-630/S-006

C.P. Pharmaceuticals International C.V.
c/o Pfizer, Inc.
Attn: Mr. Robert B. Clark
Vice President, U.S. Regulatory
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated January 27, 2005, received January 28, 2005, 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-013
VFEND [®] I.V. (voriconazole) for Injection, 10 mg/mL	21-267	S-012
VFEND [®] (voriconazole) for Oral Suspension, 45 mg/mL	21-630	S-006

We acknowledge receipt of your submissions dated August 4, 2005 and October 14, 2005. Your submission of October 14, 2005 constituted a complete response to our July 28, 2005 action letter.

These supplemental new drug applications provide for the addition of a patient package insert (PPI) to the labeling.

We have 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.

Please note that the text for the patient package insert has been combined with the most recently approved labeling dated July 7, 2005 (NDA 21-266/S-012, NDA 21-267/S-011, and NDA 21-630/S-005) and is enclosed. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

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 guidances 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 guidances specify that labeling is to 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,

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and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, these submissions should be designated "**FPL for approved supplements NDA 21-266/S-013, NDA 21-267/S-012, and NDA 21-630/S-006.**" Approval of these submissions by FDA is not required before the labeling is used.

In addition, 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 package inserts directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 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
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/s/

Renata Albrecht
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