



NDA 21-266/S-031
NDA 21-267/S-034
NDA 21-630/S-022

SUPPLEMENTS APPROVAL

Pfizer, Inc.
Attention: Ms. Anne Palestroni
Director, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Palestroni:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Drug Product Name	NDA Number	Supplement Number	Date of Supplement	Date of Receipt
VFEND [®] (voriconazole) Tablets, 50 mg and 200 mg	21-266	S-031	June 18, 2010	June 18, 2010
VFEND [®] I.V. (voriconazole) for Injection, 10 mg/mL	21-267	S-034	June 18, 2010	June 18, 2010
VFEND [®] (voriconazole) for Oral Suspension, 45 mg/mL	21-630	S-022	June 18, 2010	June 18, 2010

We acknowledge receipt of your June 28 and December 9, 2010 amendments for all three NDAs.

These Prior Approval supplemental new drug applications provide for revisions to the product labeling as they relate to the implementation plan for the January 24, 2006, Final Rule titled, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* (Federal Register Vol. 71, No. 15, 3921-3997). Specifically, these sNDAs provide for conversion of the current approved labeling to the format required by the Physician Labeling Rule in accordance with 21 CFR 201.56 and 201.57.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental new drug applications for these NDAs, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(1)(1)(i)] in MS Word format that includes the changes approved in these supplemental applications.

LABELING

Submit final printed labeling as soon as it is available, but no more than 30 days after it is printed. The final printed labeling (FPL) must be identical to the package insert.

The final printed labeling should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)”. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate these submissions “**Final Printed Labeling for approved NDA 21-266/S-031; NDA 21-267/S-034; NDA 21-630/S-022.**” Approval of these submissions by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least

24 hours prior to issuing the letter, an electronic copy of the letter to these NDAs, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 Jacquelyn Smith, M.A., Regulatory Health 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: Product Labeling

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
12/15/2010