



NDA 21266/S-041  
NDA 21267/S-053  
NDA 21630/S-031

## SUPPLEMENT APPROVAL

PF PRISM C.V.  
c/o Pfizer, Inc.  
Attention: Nadia Kirzecky  
Director, Pfizer Essential Health Global Regulatory Affairs Brands  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Kirzecky:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 19, 2016, received December 19, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 21266/S-041    VFEND (voriconazole) Tablets  
NDA 21267/S-053    VFEND I.V. (voriconazole) for Injection  
NDA 21630/S-031    VFEND (voriconazole) for Oral Suspension

These Prior Approval supplemental new drug applications propose to update the VFEND package insert to be in compliance with the FDA Pregnancy and Lactation Labeling Rule (PLLR).

Additionally, the following changes have been made:

1. In **HIGHLIGHTS**, the established pharmacological class (EPC) has been revised in the **INDICATIONS AND USAGE** section, and the lactation information was removed from the **USE IN SPECIFIC POPULATIONS** section.
2. The language for the drug-drug interaction between voriconazole and vinca alkaloids in the **DRUG INTERACTIONS** (7) section has been revised.
3. The **USE IN SPECIFIC POPULATIONS** (8) section, **Pediatric Use** (8.4) subsection has been updated.
4. The **OVERDOSAGE** (10) section has been updated.
5. The **CLINICAL PHARMACOLOGY** (12) section, **Pharmacodynamics** (12.2) and **Pharmacogenomics** (12.5) subsections have been added.

6. The **CLINICAL PHARMACOLOGY** (12) section, **Pharmacokinetics** (12.3) and **Microbiology** (12.4) subsections have been revised.
7. The **NONCLINICAL TOXICOLOGY** (13) section, **Teratogenic Effects** (13.2) subsection has been removed.

Additionally, minor editorial changes have been made throughout the labeling.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

**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 Alison Rodgers, Regulatory Project Manager, at (301)796-0797.

Sincerely,

*{See appended electronic signature page}*

Joseph Toerner, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOSEPH G TOERNER  
06/15/2017