

NDA 021266/S-052  
NDA 021267/S-062  
NDA 021630/S-041

## SUPPLEMENT APPROVAL

PF PRISM C.V.  
c/o Pfizer Inc.  
Attention: Alka Abrol  
Manager, Global Regulatory Affairs  
Hospital Business Unit, Pfizer Biopharmaceutical Group  
100 Route 206 North  
New York, NY 07977

Dear Mr. Abrol:

Please refer to your supplemental new drug applications (sNDAs) dated and received May 13, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 021266/S-052 VFEND (voriconazole) tablets, 50 mg and 200 mg  
NDA 021267/S-062 VFEND (voriconazole) for injection, 200 mg  
NDA 021630/S-041 VFEND (voriconazole) for oral suspension, 40 mg/mL

These Prior Approval sNDAs provide for revisions to the Prescribing Information (PI) to include contraindications for the use of voriconazole with glasdegib, tyrosine kinase inhibitors, eszopiclone, and tretinoin. Specifically, the following sections and subsections of the PI have been revised:

- 1) **HIGHLIGHTS OF PRESCRIBING INFORMATION:** Cisapride has been removed from **CONTRAINDICATIONS**
- 2) **FULL PRESCRIBING INFORMATION:**
  - a. **DOSAGE AND ADMINISTRATION (2)** section, **Recommended Dosing Regimen in Adults (2.3)** subsection: text has been modified.
  - b. **CONTRAINDICATIONS (4)** section: Cisapride has been removed.
  - c. **DRUG INTERACTIONS (7)** Table 11: lemborexant, glasdegib, tyrosine kinase inhibitors, eszopiclone, and tretinoin have been added, and cisapride was removed.
  - d. **USE IN SPECIFIC POPULATIONS (8)** section, **Pregnancy (8.1)** subsection, Data subheading, under *Animal Data*: text has been modified, “mg/m<sup>2</sup>” replaced with “body surface area comparison.”
  - e. **NONCLINICAL TOXICOLOGY (13)** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection: text has been modified, “mg/m<sup>2</sup>” replaced with “body surface area comparison.”

Additionally, minor editorial updates have been made throughout the PI including replacement of the name “voriconazole” with “VFEND” and addition of the manufacturer’s website at the end of the PI. Corresponding updates have been made to the Patient Package Insert and the Instructions for Use.

## **APPROVAL & LABELING**

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

## **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 [FDA.gov](http://FDA.gov).<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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 *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

## **PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

## **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}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infectives  
Office of Infectious Diseases  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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DMITRI IARIKOV  
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