NDA 21266/S-050
NDA 21267/S-060
NDA 21630/S-039

SUPPLEMENT APPROVAL

PF PRISM C.V.
c/o Pfizer Inc.
Attention: Anna Maria Gambino, MBA
Director, Global Regulatory Affairs
Hospital Business Unit, Pfizer Biopharmaceutical Group
235 East 42nd Street
New York, NY 10017

Dear Ms. Gambino:

Please refer to your supplemental new drug applications (sNDAs) dated and received August 14, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 21266/S-050	VFEND (voriconazole) tablets, 50 mg and 200 mg
NDA 21267/S-060	VFEND (voriconazole) for injection, 200 mg
NDA 21630/S-039	VFEND (voriconazole) for oral suspension, 40 mg/mL

These Prior Approval supplemental new drug applications provide for revisions to the prescribing information (PI) to include a contraindication for the use of ivabradine with voriconazole and venetoclax, and text regarding the interaction between voriconazole with ivabradine and venetoclax. Specifically, the following sections of the PI have been revised.

1) **HIGHLIGHTS OF PRESCRIBING INFORMATION,** under **RECENT MAJOR CHANGES**, Contraindications (4) has been listed and text added under **CONTRAINDICATIONS**
2) **FULL PRESCRIBING INFORMATION**
   a. **DOSAGE AND ADMINISTRATION** (2) section, **Important Administration Instructions for Use in All Patients** (2.1) subsection
   b. **CONTRAINDICATIONS** (4) section
   c. **DRUG INTERACTIONS** (7) section, including Tables 10 and 11
   d. **CLINICAL PHARMACOLOGY** (12) section, **Pharmacokinetics** (12.3) subsection, Drug Interaction Studies subheading, under **Effects of Other Drugs on Voriconazole** and **Two-Way Interactions**.
3) Minor editorial updates have been made throughout the PI including relocation of text from subsection 12.3 Pharmacokinetics to Table 11 in **DRUG INTERACTIONS** (7) to provide context for the recommended mitigation strategy and complete migration of drug-drug interaction information.
4) Corresponding updates have been made to the Patient Information.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is 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.[1] 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 Effected" (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*.[2]

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).

All promotional materials that include representations about your drug product(s) must be promptly revised to be consistent with the labeling changes approved in these supplements, 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

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 or Medication Guide
    - Instructions for Use

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.

/s/

DMITRI IARIKOV
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