NDA 021266/S-051
NDA 021267/S-061
NDA 021630/S-040

**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 March 05, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 021266/S-051 VFEND (voriconazole) tablets, 50 mg and 200 mg
NDA 021267/S-061 VFEND (voriconazole) for injection, 200 mg
NDA 021630/S-040 VFEND (voriconazole) for oral suspension, 40 mg/mL

These Prior Approval sNDAs provide for revisions to the prescribing information (PI) to include a contraindication for the use of lurasidone with voriconazole. Specifically, the following sections of the PI have been revised:

1) **HIGHLIGHTS OF PRESCRIBING INFORMATION**: under **RECENT MAJOR CHANGES**
2) **FULL PRESCRIBING INFORMATION:**
   a. **DOSAGE AND ADMINISTRATION (2)** section, **Dosage Modifications in Patients with Renal Impairment (2.6)** subsection, **Adult Patients**
   b. **DRUG INTERACTIONS (7)** section, including Table 11; lurasidone has been added and text regarding midazolam has been modified.
   c. [redacted] (b) (4)

Additionally, minor editorial updates have been made throughout the PI including replacement of the term, "adverse events" with "adverse reactions" and corresponding updates have been made to the Patient Package Insert.

## 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.[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 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).

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[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.

**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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