NDA 21266/S-048
NDA 21267/S-058
NDA 21630/S-037

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 March 2, 2020, received March 2, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 21266/S-048	VFEND (voriconazole) tablets, 50 mg and 200 mg
NDA 21267/S-058	VFEND (voriconazole) for injection, 200 mg
NDA 21630/S-037	VFEND (voriconazole) for oral suspension, 40 mg/mL

These Prior Approval supplemental new drug applications provide for the following revisions to the prescribing information (PI):

(1) **Serious Exfoliative Cutaneous Adverse Reactions (5.5)** has been revised to read **Severe Cutaneous Adverse Reactions (5.5)** in the **WARNINGS AND PRECAUTIONS (5)** section.
(2) Toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) has been added to the **Severe Cutaneous Adverse Reactions (5.5)** subsection.
(3) DRESS has been added to the **ADVERSE REACTIONS (6)** section, **Clinical Trials Experience (6.1)** subsection, Dermatological Reactions and the **Postmarketing Experience in Adult and Pediatric Patients (6.2)** subsection, Adults.

Additionally, minor editorial revisions have been made throughout the PI.

APPROVAL & LABELING

We have completed our review of these applications. 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).

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

[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.

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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