DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21630/S-033

SUPPLEMENT APPROVAL

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

Dear Ms. Kirzecky:

Please refer to your Supplemental New Drug Application (sNDA) dated June 27, 2018, received June 27, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vfend (voriconazole) for oral suspension, 40 mg/mL.

This Prior Approval supplemental new drug application provides for the following revisions to the carton and container labeling:

1) Replacement of "45g" and "(75 mL when reconstituted)" with the final volume of "75 mL (when reconstituted)" on the principal display panel.
2) Removal of the space between the "46°" and "F" under the header "Before reconstitution" on both the container label and carton labeling.
3) Revision of the storage statements to read, "*Before reconstitution:* Store dry powder refrigerated at 2°C to 8°C (36°F to 46°F). *After reconstitution:* Store suspension at controlled room temperature, 15°C to 30°C (59°F to 86°F). Do not refrigerate or freeze. ANY UNUSED SUSPENSION SHOULD BE DISCARDED 14 DAYS AFTER RECONSTITUTION" on both the container label and carton label.

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for

industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21630/S-033**." Approval of this submission by FDA is not required before the labeling is used.

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-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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
10/04/2018