NDA 021632/S-027
NDA 021632/S-029

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Vicuron Holdings LLC, a subsidiary of Pfizer Inc.
Attention: Michele Burtness, PharmD
Senior Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Burtness:

Please refer to your supplemental new drug applications (sNDAs) dated and received November 22, 2019, (S-027) and March 25, 2020, (S-029), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ERAXIS (anidulafungin) for injection, 50 mg/vial and 100 mg/vial.

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

Supplement 027	Addition of the pediatric population 1 month of age and older to the approved indication for treatment of candidemia and other forms of *Candida* infections (intra-abdominal abscess and peritonitis); this supplement was submitted to fulfill deferred postmarketing requirement (PMR) #311-1, listed in the February 17, 2006 NDA approval letter.
Supplement 029	Addition of Hereditary Fructose Intolerance to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, FULL PRESCRIBING INFORMATION: CONTRAINDICATIONS (4)**, **WARNINGS AND PRECAUTIONS (5)**, **Patients with Hereditary Fructose Intolerance (HFI) (5.4)**, **USE IN SPECIFIC POPULATIONS (8), Pediatric Use (8.4)**, and **PATIENT COUNSELING INFORMATION (17)**, **Hereditary Fructose Intolerance (17.4)**.

Additionally, revisions have been made throughout labeling to the applicable sections of the PI based on the information submitted in both supplements.

Editorial and formatting changes have also been made throughout labeling inclusive of the revision of ‘single-use’ to read as ‘single dose’ in the PI and the carton and container labeling.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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), 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 this NDA, 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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days

[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.

after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 021632/S-027 and S-029**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application. A waiver was granted for pediatric patients less than one month of age on May 7, 2014.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated November 22, 2019, containing the final report for the following postmarketing requirement listed in the February 17, 2006 approval letter.

311-1 Deferred pediatric study under PREA for the treatment of candidemia and other forms of *Candida* infections (intra-abdominal abscess and peritonitis) in pediatric patients ages zero months to sixteen years of age.

Supplement 27 provided the final study report for Protocol A8851008, "A Prospective, Open-Label Study to Assess the Pharmacokinetics, Safety & Efficacy of Anidulafungin when Used to Treat Children with Invasive Candidiasis, Including Candidemia." conducted to fulfill PMR 311-1.

We have reviewed your submission and conclude that the above requirement was fulfilled. This completes the postmarketing requirement acknowledged in our February 17, 2006 letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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).

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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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.

/s/

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