DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21632/S-011

SUPPLEMENT APPROVAL

Vicuron Holdings LLC
a subsidiary of Pfizer, Inc.
Attention: Anthony Helstosky
Global Regulatory Lead, Worldwide Regulatory Strategy
445 Eastern Point Road
Groton, CT 06340

Dear Mr. Helstosky:

Please refer to your Supplemental New Drug Application (sNDA) dated June 26, 2009, received June 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ERAXIS (anidulafungin) Powder for Injection.

We acknowledge receipt of your amendments dated December 10, 2010, May 26, August 12, September 16, and December 15, 2011, and March 2, 2012.

The December 10, 2010, submission constituted a complete response to our December 22, 2009, action letter.

This "Prior Approval" supplemental new drug application proposes revisions to the package insert to comply with the requirements of the Final Rule: Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products, published January 24, 2006, and addresses the deficiencies communicated in the December 22, 2009, action letter.

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 labeling, text for the package insert submitted March 2, 2012, with the minor editorial revisions as listed below.

(1) [redacted] (b) (4) has been revised to read 'adverse reactions' in the **HIGHLIGHTS OF PRESCRIBING INFORMATION, WARNINGS AND PRECAUTIONS** section, the **5 WARNINGS AND PRECAUTIONS** section, **5.2 Hypersensitivity** subsection, and the **17 PATIENT COUNSELING INFORMATION** section, 17.2 **Hypersensitivity** subsection.

(2) The word 'bronchospasm' has been added between the words 'pruritus' and 'dyspnea' in the second bullet in the **HIGHLIGHTS OF PRESCRIBING INFORMATION, WARNINGS AND PRECAUTIONS** section.

(3) The following changes have been made in 12.4 Microbiology:

12.4 Microbiology

Activity *in vitro*
Anidulafungin has been shown to be active against *Candida albicans*, *C. glabrata*, *C. parapsilosis*, and *C. tropicalis* both in vitro and in clinical infections as described in INDICATIONS AND USAGE (b) (4) and CLINICAL STUDIES sections (b) (4) Because of the potential for reduced susceptibility to anidulafungin, it is recommended that susceptibility be determined by a standardized method[15] (b)

Anidulafungin minimal inhibitory concentrations (MICs) were determined for isolates of *Candida* spp. obtained during clinical studies using a standardized method[15] (b) (4) However, no correlation between *in vitro* activity (b) (4) as determined by this method and clinical outcome was established.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
07/20/2012