DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-632

Vicuron Pharmaceuticals Inc., a subsidiary of Pfizer
Atttention: Maureen H. Garvey, Ph.D.
Senior Director, Worldwide Regulatory Affairs and Quality Assurance
235 East 42nd Street
New York, NY 10017

Dear Dr. Garvey:

Please refer to your supplemental new drug application (sNDA) dated August 2, 2006, received August 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ERAXIS™ (anidulafungin) for Injection, 50 mg.

We acknowledge receipt of your submissions dated December 15, 2006 and January 25, 2007.

This supplemental new drug application provides for changes to the **CLINICAL PHARMACOLOGY/ Distribution** and **Drug Interaction Studies** subsections as follows (underline indicates addition; strikethrough indicates deletion):

> **CLINICAL PHARMACOLOGY/Distribution**
> Anidulafungin is ~~moderately~~ extensively bound (>99%) to human plasma proteins ~~in humans (84%)~~.
>
> **CLINICAL PHARMACOLOGY/ Drug Interaction Studies**
> *In vitro* studies showed that anidulafungin is not metabolized by human cytochrome P450 or by isolated human hepatocytes, and does not significantly inhibit the activities of ~~clinically important~~ human CYP isoforms (1A2, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4) at clinically relevant concentrations.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Kristen Miller, Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Renata Albrecht

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