**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-632/S-002

Vicuron Pharmaceuticals Inc., a subsidiary of Pfizer
Attention: 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 dated March 27, 2006, received March 28, 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 submission dated May 11, 2006.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert (additions are double underlined and deletions are ~~strikethrough~~):

The **DOSAGE AND ADMINISTRATION/ Preparation of ERAXIS for Administration** subsection was revised to read:

~~*Dilution and Infusion*~~
~~Aseptically transfer the contents of the reconstituted vial(s) into an IV bag (or bottle) containing either 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP (normal saline) to provide an infusion solution concentration of 0.5 mg/mL. Table 10 provides the number of vials and volumes required for each dose.~~

~~TABLE 10. DILUTION REQUIREMENTS FOR ERAXIS ADMINISTRATION~~

| ~~Dose~~ | ~~Number of 50 mg Vials~~ | ~~Total Reconstituted Volume~~ | ~~Diluent Volume Required~~ | ~~Total Infusion Volume~~ |
|---|---|---|---|---|
| ~~50 mg~~ | ~~1~~ | ~~15 mL~~ | ~~85 mL~~ | ~~100 mL~~ |
| ~~100 mg~~ | ~~2~~ | ~~30 mL~~ | ~~170 mL~~ | ~~200 mL~~ |
| ~~200 mg~~ | ~~4~~ | ~~60 mL~~ | ~~340 mL~~ | ~~400 mL~~ |

*Dilution and Infusion*
Aseptically transfer the contents of the reconstituted vial(s) into the appropriately sized IV bag (or bottle) containing either 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP (normal saline). Table 10 provides the number of vials, volumes and infusion solution concentration for each dose.

**Table 10. Dilution requirements for ERAXIS Administration**

| Dose | Number of 50 mg Vials | Total Reconstituted Volume | Infusion Volume [a] | Total Infusion Volume | Infusion Solution Concentration |
|---|---|---|---|---|---|
| 50 mg | 1 | 15 mL | 100 mL | 115 mL | 0.43 mg/mL |
| 100 mg | 2 | 30 mL | 250 mL | 280 mL | 0.36 mg/mL |
| 200 mg | 4 | 60 mL | 500 mL | 560 mL | 0.36 mg/mL |

[a] Either 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP (normal saline)

Your May 11, 2006 submission contained final printed labeling (FPL) that reflects the above agreed upon changes.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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

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/s/

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Renata Albrecht

8/7/2006 11:27:41 AM