DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-632/S-003

Vicuron Pharmaceuticals, Inc.
A subsidiary of Pfizer
Attention: Maureen Garvey, PhD
Senior Director, Worldwide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Dr. Garvey:

Please refer to your supplemental new drug application (NDA) dated and received July 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ERAXIS™ (anidulafungin) for Injection, 50mg.

We acknowledge your submission dated September 28, 2006, which provided information on bacterial endotoxin testing methodology and specifications.

This supplemental new drug application originally proposed the following changes:

- Addition of a 100 mg/vial presentation for drug product and a 30 mL vial presentation for Diluent.
- (b)(4) and revision of specifications for the 50 mg/vial drug product and 15 mL/vial diluent presentation.
- Minor revisions resulting from clarifications, corrections and updates.

We also acknowledge your submission dated November 9, 2006. In this submission, you requested the withdrawal of the originally proposed (b)(4) for the 50 mg/mL vial drug product and 15 mL/vial diluent presentation. Therefore, this supplemental new application now provides for:

- Revisions of specifications to the 50 mg/vial drug product and 15 mL/vial diluent presentation.
- Addition of a 100 mg/vial presentation for drug product and a 30 mL vial presentation for the diluent, that includes changes to the **DESCRIPTION, DOSAGE and ADMINISTRATION,** and **HOW SUPPLIED** sections of the package insert, as well as a new carton and container labels for the 100 mg vial presentation.
- Minor revisions resulting from clarifications, corrections and updates.

The proposed changes for the package insert are listed below. Deletions are indicated by ~~strikeout~~ and additions are indicated by double underline .

1. In the **DESCRIPTION** section, second paragraph the text was revised to read as follows:

   ERAXIS (anidulafungin) is 1-[(4R,5R)-4,5-Dihydroxy-N^2-[[4''-(pentyloxy)[1,1':4',1''-terphenyl]-4-yl]carbonyl]-L-ornithine]echinocandin B**.** Anidulafungin is a white to off-white powder that is practically insoluble in water and slightly soluble in ethanol. In addition to the active ingredient, anidulafungin, ERAXIS for Injection contains the following inactive ingredients:
   50mg/vial - fructose (50 mg), mannitol (250 mg), polysorbate 80 (125 mg), tartaric acid (5.6 mg), and sodium hydroxide and/or hydrochloric acid for pH adjustment.
   100mg/vial - fructose (100 mg), mannitol (500mg), polysorbate 80 (250 mg), tartaric acid (11.2 mg), and sodium hydroxide and/or hydrochloric acid for pH adjustment.

2. In the **DOSAGE AND ADMINISTRATION** section, **Preparation of ERAXIS for Administration** subsection, 2nd and 3rd paragraphs were revised to read as follows:

   Reconstitution 50mg/vial
   Aseptically reconstitute each 50 mg vial with 15 mL of the companion diluent (20% (w/w) Dehydrated Alcohol in Water for Injection) to provide a concentration of 3.33 mg/mL. The reconstituted solution should be stored at 25ºC (77ºF); excursions permitted to 15-30ºC (59-86ºF) (see USP Controlled Room Temperature). Do not freeze. The reconstituted solution must be further diluted and administered within 24 hours.

   Reconstitution 100mg/vial
   Aseptically reconstitute each 100 mg vial with 30 mL of the companion diluent (20% (w/w) Dehydrated Alcohol in Water for Injection) to provide a concentration of 3.33 mg/mL. The reconstituted solution should be stored at 25ºC (77ºF); excursions permitted to 15-30ºC (59-86ºF) (see USP Controlled Room Temperature). Do not freeze. The reconstituted solution must be further diluted and administered within 24 hours.

3. In the **DOSAGE AND ADMINISTRATION** section, **Preparation of ERAXIS for Administration** subsection, 4th paragraph along with table 10, *Dilution and Infusion* subsection the text was revised to read as follows:

   Aseptically transfer the contents of the reconstituted vial(s) into (b)(4) appropriately sized IV bag (or bottle) containing either 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP (normal saline) (b)(4).
   Table 10 provides the number of Unit Packs (ERAXIS vial and companion diluent vial, see HOW SUPPLIED) (b)(4) volumes and infusion solution concentration (b)(4) for each dose.

TABLE 10. DILUTION REQUIREMENTS FOR ERAXIS ADMINISTRATION					
Dose	(b)(4) Number of Unit Packs Required	Total Reconstituted Volume Required	Infusion Volume [a]	Total Infusion Volume	Infusion Solution Concentration
50 mg	1-50 mg	15 mL	100 mL	115 mL	0.43 mg/mL
100 mg	2-50 mg OR 1-100 mg	30 mL	250 mL	280 mL	0.36 mg/mL
200 mg	4-50 mg OR 2-100 mg	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)

4. The **HOW SUPPLIED** section, was revised to read as follows:

ERAXIS (anidulafungin) for Injection, (b)(4) is supplied in a single-use vial of sterile, lyophilized, preservative-free, powder. The companion single-use diluent vial contains (b)(4) % (w/w) Dehydrated Alcohol in Water for Injection. ERAXIS (anidulafungin) is available in the following packaging configuration:

Single Use Unit Pack (containing ERAXIS (b)(4) 50 mg vial and 15 mL Diluent vial)
NDC 0049-1010-28 One - 50 mg vial and 15 mL diluent vial

Single Use Unit Pack (containing ERAXIS 100 mg vial and 30 mL Diluent vial)
NDC 0049-0115-28One - 100 mg vial and 30 mL diluent vial

(b)(4)

We have completed our review of this application, as amended, and it is approved effective on the date of this letter, for use as recommended in the package insert and carton and container labels submitted on July 12, 2006, and with the revised bacterial endotoxin specifications as described in your submission dated September 28, 2006.

Within 21 days of the date of this letter, submit 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 public dissemination.

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, call Judit Milstein, Chief Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

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

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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Enclosure: Package Insert
Carton and Container Label

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
11/14/2006 06:35:38 PM

Hasmukh Patel
11/15/2006 09:57:55 AM