DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-632/S-006

Vicuron Pharmaceuticals, Inc.
Attention: Maureen H. Garvey, PhD
Senior Director, Worldwide Regulatory Strategy
235 East, 42nd Street
New York, NY 10017

Dear Dr. Garvey:

Please refer to your supplemental new drug application dated and received on May 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ERAXIS™ (anidulafungin) for Injection.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert (~~strikethrough~~ indicates deleted text and underline indicates added text):

1. In the **DOSAGE AND ADMINISTRATION/Preparation of ERAXIS for administration**/*Reconstitution 50 mg/vial* subsection, the second to the last sentence has been revised to read:

   Do not refrigerate or freeze

2. In the **DOSAGE AND ADMINISTRATION/Preparation of ERAXIS for administration**/*Reconstitution 100 mg/vial* subsection, the second to the last sentence has been revised to read:

   Do not refrigerate or freeze

3. In the **DOSAGE AND ADMINISTRATION/Preparation of ERAXIS for administration/***Dilution and Infusion* subsection, the last sentence of the last paragraph has been revised to read:

   Do not refrigerate or freeze

4. In the **STORAGE/Reconstituted vials** subsection, the second to the last sentence has been revised to read:

   Do not refrigerate or freeze

5. In the **STORAGE/Diluted product** subsection, the last sentence has been revised to read:

   Do not refrigerate or freeze

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the labeling on May 11, 2007.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kristen Miller, Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
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/

Steven Gitterman
11/9/2007 08:16:45 AM
Steven Gitterman, M.D., Ph.D., for Renata Albrecht