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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-632
NDA 21-948

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-632
NDA 21-948

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 new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ERAXIS™ (anidulafungin) for Injection, 50 mg.

1. NDA 21-632

NDA 21-632, originally submitted on April 25, 2003, received an approvable letter on May 21, 2004. The May 27, 2005 submission to this NDA constituted a complete response to our May 21, 2004 approvable letter. A second approvable letter was issued for NDA 21-632 on November 25, 2005 requesting a revised package insert and carton labeling. Your January 24, 2006 submission, received on January 25, 2006, constituted a complete response to our November 25, 2005 approvable letter.

This new drug application provides for the use of ERAXIS™ (anidulafungin) for Injection for the treatment of patients with esophageal candidiasis.

We acknowledge receipt of your submissions dated:

December 2, 2005 (2)
January 4, 2006 (2)
January 13, 2006 (2)
January 27, 2006
February 13, 2006

2. NDA 21-948

NDA 21-948 was submitted on August 18, 2005 and received on August 18, 2005. This new drug application provides for the use of Eraxis (anidulafungin) for Injection for the treatment of patients with candidemia and other forms of *Candida* infections (intra-abdominal abscess and peritonitis).

We acknowledge receipt of your submissions dated:

September 16, 2005
November 1, 2005
November 4, 2005
December 2, 2005
January 4, 2006
January 13, 2006
January 24, 2006
January 27, 2006
February 13, 2006
February 14, 2006

We completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved NDAs 21-632 and 21-948**." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for the indication of esophageal candidiasis for ages zero months to sixteen years and deferring pediatric studies for the indication of candidemia and other forms of *Candida* infections (intra-abdominal abscess and peritonitis) for ages zero months to sixteen years for these applications.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of candidemia and other forms of *Candida* infections (intra-abdominal abscess and peritonitis) in pediatric patients ages zero months to sixteen years of age.

   Final Report Submission: February 17, 2011

Submit final study reports to NDA 21-632. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-632 for this drug product, not to NDA 21-948. In the future, do not make submissions to NDA 21-948 except for the final printed labeling requested above.

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

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

Sincerely,

{See appended electronic signature page}

Mark Goldberger, M.D., M.P.H.
Director
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Edward Cox
2/17/2006 04:18:43 PM
for Mark J. Goldberger, MD, MPH