DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-476/S-012

Sepracor, Inc.
Attention: Kimberly Parthum, Ph.D.
Director, Regulatory Compliance
84 Waterford Drive
Marlborough, MA 01752-7010

Dear Dr. Parthum:

Please refer to your supplemental new drug application dated April 8, 2008, received April 8, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LUNESTA® (eszopiclone) Tablets.

We acknowledge receipt of your submissions dated October 3, 2008, October 9, 2008 and December 5, 2008.

This supplemental new drug application provides for a new packaging configuration (30 count bottle for LUNESTA 1 mg tablet).

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling on April 8, 2008.

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
HFD-001, Suite 5100
5515 Security Lane
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 Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosures

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

/s/

Jim Vidra

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