DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-476/S-005, S-008

Sepracor, Inc.
84 Waterford Drive
Marlborough, MA 01752

Attention: Kathleen Grim
Executive Director of Regulatory Compliance

Dear Ms. Grim:

Please refer to the supplemental new drug applications noted below submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lunesta (eszopiclone), 1, 2 and 3 mg Tablets.

Application	Submitted on:	Received on:	Provides for:
S-005	April 25, 2007	April , 2007	"Changes Being Effected" Supplement; revisions to Warnings and Precautions section.
S-008	August 9, 2007	August , 2007	"Prior Approval" Supplement: Medication Guide.

We acknowledge receipt of your submissions dated August 1, 2007, August 9, 2007, November 28, 2007, and January 18, 2008.

We note that the "Changes Being Effected" supplemental new drug application **S-005** provides for changes to the package insert and was submitted in response to the Agency's February 14, 2006 and December 6, 2006 letters requesting a class labeling change for the sedative-hypnotic drug group.

We note that Supplemental Application **S-008** was submitted in response to an Agency request for Medication Guide that was described in our December 4, 2006 letter.

We have completed our review of the supplemental applications **(S-005, S-008)**, and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed upon labeling text submitted on January 18, 2008.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and medication guide) submitted on January 18, 2008.

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 the submission "**FPL for approved supplement NDA 21-476/S-005, S-008**."

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 this division/ the Division of Neurology 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
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Cathleen Michaloski, MPH, Regulatory Project Manager, at (301)-796-1123.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director, Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

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

/s/

Russell Katz

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