DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-476

Sepracor Inc.
Attention: Cynthia L Kirk, Ph.D.
Vice President, Regulatory Affairs
84 Waterford Drive
Marlborough, MA 01752

Dear Dr. Kirk:

Please refer to your new drug application (NDA) dated January 20, 2003, received January 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lunesta (eszopiclone) 1mg, 2mg, and 3mg tablets.

We acknowledge receipt of your additional submissions dated:

March 12, 2003	June 13, 2003	October 16, 2003	March 5, 2004	September 30, 2004
March 17, 2003	June 18, 2003	November 11, 2003	March 9, 2004	November 8, 2004
March 18, 2003	June 24, 2003	November 25, 2003	April 1, 2004	November 9, 2004
March 19, 2003	June 30, 2003	December 16, 2003	May 20, 2004	November 19, 2004
March 24, 2003	July 8, 2003	December 18, 2003	June 14, 2004	November 22, 2004
March 25, 2003	July 15, 2003	December 22, 2003	August 11, 2004	November 24, 2004
April 15, 2003	July 25, 2003	February 6, 2004	August 20, 2004	
May 29, 2003	August 28, 2003	February 11, 2004	August 26, 2004	
June 5, 2003	October 14, 2003	March 2, 2004	September 29, 2004	

Your June 14, 2004 submission constituted a complete response to our February 27, 2004 action letter.

This new drug application provides for the use of Lunesta (eszopiclone) Tablets in the treatment of insomnia.

Labeling

We have completed our review of this application, as amended. It is 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 and text for the patient package insert). With regard to immediate container and carton labels, we note that the labels submitted November 24, 2004 do not accurately reflect your tradename "Lunesta." Therefore, please submit corrected FPL as agreed to in a December 14, 2004 telephone conversation between Dr. Renmeet Gujral of the Division and yourself. 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 this submission "**FPL for approved NDA 21-476**." Approval of this submission by FDA is not required before the labeling is used.

Pediatric Research Equity Act (PREA)
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 ages 0 to less than 3 years and deferring pediatric studies for ages 3 to 17 years for this application.

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 insomnia in pediatric patients ages 3 to 17 years.

Final Report Submission: March 2010

Submit the final study report to this NDA. For administrative purposes, all submissions related to this pedatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

Chem(b)(4)-- nufacturing and Controls
1. A (b)(4) re-test date for eszopiclone drug substance is granted.
2. A 24 month expiry is granted for the 2 mg and 3 mg strength tablets in (b)(4) bottles and (b)(4) blisters.
3. A 15 month expiry is granted for the 1 mg light blue tablet in (b)(4) bottles.

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

Promotional Materials
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 Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MedWatch

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.

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 Renmeet Gujral, Pharm.D., Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
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/

Robert Temple

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