DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-912/S-001

Sepracor Inc.
84 Waterford Drive
Marlborough, MA 01752

Attention: John Salveta
Associate Director, Regulatory Affairs

Dear Mr. Salveta:

Please refer to your supplemental new drug application dated June 20, 2007, received June 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brovana.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the packaging of the product from a single vial pouch to a 4-foil pouch configuration.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below as communicated to you on December 20, 2007, in a telephone conversation with Ms. Akilah Green.

1. Use consistent language throughout the Medication Guide and Patient Instruction for Use when describing the vials of Brovana.

2. Use the term, "Ready to Use," consistently throughout the labels and labeling to describe the Brovana vials so that it clearly conveys the product needs no further dilution prior to administration and minimizes the potential for a medication error.

3. Eliminate the supplementary expression of the strength (15 mcg) at the top of the pouch above the proprietary name to reduce the potential it may be confused with the net quantity of the pouch.

4. Relocate the dosage form and product strength so that it is immediately underneath the proprietary and established names to improve readability.

5. For the 4-vial foil pouch, a 18-month expiration dating period at refrigerated conditions is granted.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed above, the enclosed labeling (text for the package insert, text for the patient package insert, text for the Medication Guide) submitted June 20, 2007. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 21-912."

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and/or submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-912**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Pulmonary and Allergy 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

In addition, all future relevant changes to the Package Insert should be reflected in the Medication Guide.

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 Ms. Akilah Green, Regulatory Project Manager, at (301) 301-796-1219.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
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/

Badrul Chowdhury

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