DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-837/S-010

Sepracor, Inc.
84 Waterford Drive
Marlborough, MA 01752

Attention: Prabu Nambiar, Ph.D., RAC
Director, Technical Regulatory Affairs

Dear Dr. Nambiar:

Please refer to your supplemental new drug application dated March 29, 2002, received April 1, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Xopenex (levalbuterol HCl) Inhalation Solution.

We acknowledge receipt of your submissions dated September 4, 2002, December 3, 2002, March 17, July 16, and July 17, 2003.

Your submission of March 17, 2003 constituted a complete response to our August 1, 2002, action letter.

This supplemental new drug application provides for the addition of a new strength (1.25 mg/0.5 mL) of the drug product.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. Please note that the expiration dating period for this strength (1.25 mg/0.5 mL) of the drug product is 18 months. In addition, we have the following comment.

We remind you of your agreements to revise final printed labels (package insert, foil-pouch label, carton label, etc.) for clarity prior to implementation and to provide representative samples both for the final printed labels and vial samples to the Agency, prior to the launch of the drug product.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels as submitted on March 17, 2003, foil pouch label as submitted on July 16, 2003, and package insert as submitted on July 17, 2003).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-837/S-010." Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit four copies of the introductory promotional materials 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 Pulmonary and Allergy Drug Products, one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials and the package insert(s) directly to:

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

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Akilah Green, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
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/

Guiragos Poochikian

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