DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-837\S-020

Sepracor, Inc.
84 Waterford Drive
Marlborough, MA 01752-7010

Attention: Jerry Klimek
Senior Director, Regulatory Affairs

Dear Mr. Klimek:

Please refer to your supplemental new drug application dated December 22, 2006, received December 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xopenex (levalbuterol HCL) Inhalation Solution and Xopenex (levalbuterol HCL) Inhalation Solution Concentrate.

This "Changes Being Effected" supplemental new drug application provides for the addition of Metabolism and Elimination, and Special Populations subsection under the CLINICAL PHARMACOLOGY section and a POSTMARKETING ADVERSE REACTIONS section to the Package Insert for consistency with the approved labeling for Xopenex HFA (levalbuterol HCL) Inhalation Aerosol.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 22, 2005.

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 20857

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 Ms. Akilah Green, Senior Regulatory Management Officer, at (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

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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