DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-730/S-008

Sepracor Inc.
84 Waterford Drive
Marlborough, MA 01752

Attention: Seth Shapiro
Associate Director, Technical Regulatory Affairs

Dear Mr. Shapiro:

Please refer to your supplemental new drug application dated August 16, 2006, received August 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated November 7, 2006, and October 5, 2007.

Your submission of October 5, 2007, constituted a complete response to our December 14, 2006, action letter.

This supplemental new drug application provide for an additional presentation of Xopenex HFA 45 mcg per actuation with 80 actuations.

We have 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 in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on August 16, 2006.

In addition, we have the following comment:

> We are granting an expiry dating of 15 months for the 80 actuation Xopenex drug product based on the DCU stability data.

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted October 5, 2007, 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 21-730**." 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 this division 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We remind you of your agreements listed in your amendments dated February 4, and 5, 2008, to complete the following:

1. Conduct investigation on the root causes of the observed discrepancies between the 80 actuations and 200 actuations drug products in terms of DCU stability data, and take corrective actions.

2. Submit any future extension of the shelf life for the 80 actuation presentation beyond 15 months as a CBE supplement, per Guidance for Industry, Changes to an Approved NDA or ANDA (1999), XI (B), and supported by real time data of all critical quality attributes.

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 Drug 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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