CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-730

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-730

Sepracor Inc.
84 Waterford Drive
Marlborough, Massachusetts 01752

Attention: Jerry Klimek
Senior Director Regulatory Affairs

Dear Mr. Klimek:

Please refer to your new drug application (NDA) dated May 11, 2004, received May 12, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated July 6, August 19, September 9, October 20, and 29, November 23, and December 24, 2004, and January 17, February 4, and 22, and 28, March 3, 10 and 11, 2005.

This new drug application provides for the use of Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol for treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

We 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 submitted labeling (package insert and patient instructions for use submitted March 11, 2005, immediate container and carton labels submitted March 10, 2005). 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.

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 21-730**." Approval of this submission by FDA is not required before the labeling is used.

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 deferring submission of your pediatric studies for ages 0 to < 4 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 these postmarketing studies 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 bronchospasm in children with reversible obstructive airway in pediatric patients ages 0 to < 4 years.

   Final Report Submission: March 31, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments.**"

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:

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

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

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 agreement listed in your amendment dated February 4, 2005, to complete the following:

> In accordance with CDER's Guidance to Industry on Dose Counters, Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol will have a dose-indicating device.
>
> It is our expectation that you will provide a prior approval supplement to incorporate the dose-indicating device for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol within one year of approval.

If you have any questions, call Ms. Akilah Green, Regulatory Project Manager, at (301) 301-827-5585.

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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