



NDA 21-730/S-006

Sepracor Inc.
84 Waterford Drive
Marlborough, MA 01752

Attention: Jerry Klimek
Senior Director, Regulatory Affairs

Dear Mr. Klimek:

Please refer to your supplemental new drug application dated October 17, 2005, received October 18, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for a change to the NDC number and the addition of the text "PROFESSIONAL SAMPLE NOT FOR SALE OR REIMBURSEMENT."

We completed our review of this application. This application 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 (immediate container and carton labels submitted October 17, 2005).

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 supplement NDA 21-730/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

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, Senior Regulatory Management Officer, at (301) 796-1219.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch 7, Division of Postmarketing Evaluation
Office of New Drug Quality Assessment
Center of 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/

Jim Vidra
4/4/2006 01:03:05 PM