DOCUMENT INFORMATION PAGE

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Application #(s):	NDA 20-837/S-043
Communication Type:	Correspondence
Communication Group:	sNDA Action
Communication Name:	Approval
Communication ID:	COR-SNDAACTION-05
Drafted by:	Ramsey/March 20, 2015
Clearance History by:	Barnes/March 30, 2015; Starke/March 31, 2015; Maynard/March 31, 2015; Chowdhury/March 31, 2015
Finalized:	Ramsey/March 31, 2015
Filename:	
Signatory Authority:	Division Director or Deputy Division Director. Person who is covering for the signatory authority can sign on their behalf (i.e., the signature block on the letter will not change)
Use Statement:	Use to notify applicant of an approval action for a supplemental application that includes changes to the labels or labeling
Notes:	USE "sNDA Approval [OTC ONLY]" template for Over-the-Counter sNDA Approvals USE COR-SNDAACTION-06 FOR sNDA CMC APPROVALS USE COR-SNDAACTION-09 FOR sNDA TENTATIVE APPROVALS If supplement approval also fulfills a PMR/PMC, this letter will need to be double-coded as PMR-PMC Fulfilled.

Version: 02/26/2015

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-837/S-043

SUPPLEMENT APPROVAL

Oak Pharmaceuticals
1925 West Field Court Suite 300
Lake Forest, Il 60045

Attention: Sam Boddapati, PhD
Senior Vice President, Regulatory Affairs

Dear Dr. Boddapati:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2014, received June 30, 3014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xopenex (levalbuterol hydrochloride) inhalation solution.

We acknowledge receipt of your amendment dated December 11, 2014.

This Prior Approval supplemental new drug application provides for revisions to the foil pouch labeling.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on December 11, 2014 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 Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008). 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 20-837/S-043." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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 Angela Ramsey, Senior Program Management Officer, at (301) 796-2284.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

6.360" Finished Cut Off

5.50" Cut Web Width

Each 0.5 mL unit-dose vial contains 1.25 mg of levalbuterol as the hydrochloride salt in an aqueous solution containing sodium chloride and hydrochloric acid to adjust pH to 4.0. Contains no preservatives.

Dilute Before Use

Protect from light. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Discard if solution is not colorless.

Use only as directed by your physician.

Do not exceed recommended dose.

Area Reserved for CMO Verification Code

NDC 17478-171-01

One 0.5 mL Sterile Unit-Dose Vial

Open Foil Pouch Just Prior to Administration

Dilute Before Use

Xopenex®
(levalbuterol HCl)
Inhalation Solution
Concentrate
*1.25 mg/0.5 mL**

***Potency expressed as levalbuterol**

Keep out of reach of children. Rx Only.

Attention Pharmacist: Detach "Patient's Information" from package insert and dispense with product.

Area Reserved for Lot/Exp

AKORN

Distributed by: **Akorn, Inc.**
Lake Forest, IL 60045

Manufactured for: **Oak Pharmaceuticals, Inc.**

BARCODE

XPCAP Rev. 12/14

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/s/

BADRUL A CHOWDHURY
03/31/2015