DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21730/S-036

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT
RELEASE FROM
POSTMARKETING REQUIREMENT

Sunovion Pharmaceuticals Inc.
84 Waterford Drive
Marlborough, MA 01752-7010

Attention: Kimberly Parthum, Ph.D.
Director, Regulatory Affairs

Dear Dr. Parthum:

Please refer to your Supplemental New Drug Application (sNDA) dated May 27, 2014, received May 27, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol, 45 mcg/Actuation.

We acknowledge receipt of your amendments dated July 3, August 15, and November 26, 2014, and January 15 and 27, and February 6, 2015.

This Prior Approval supplemental new drug application proposes to update the labeling for Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol with information regarding a clinical trial in children less than 4 years of age, and to fulfill the Pediatric Research Equity Act (PREA) post marketing requirement as outlined in the March 11, 2005 approval letter.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, text for the patient package insert, and text for the information for use with the addition of any labeling

changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated May 27, 2014, containing the final report for the following postmarketing requirement listed in the March 11, 2005, approval letter.

730-1 Deferred pediatric study under PREA for the treatment of bronchospasm in children with reversible obstructive airway in pediatric patients ages 0 to less than 4 years.

The following two studies were required to satisfy the above PREA requirement.

Study 051-359 – A 4 week safety, efficacy, and tolerability study with Xopenex HFA in children with asthma from birth to less than 4 years of age

Study 051-361 – A safety and tolerability study with Xopenex HFA in children with reactive airways disease from birth to less than 4 years of age in the acute setting

We have reviewed your submission containing the results from Study 051-359 and conclude that the requirement for Study 051-359 has been fulfilled.

RELEASE FROM POSTMARKETING REQUIREMENT

We also refer to your submission, dated December 15, 2014, requesting waiver of the requirement for Study 051-361

We have reviewed your submission and have determined that you are released from the requirement for Study 051-361 because this study will not provide any additional safety or

efficacy data for Xopenex HFA beyond what has been obtained and included in the product labeling.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our March 11, 2005, letter.

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 Carol F. Hill, Safety Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
03/12/2015