DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200603/S-010 and S-011

SUPPLEMENT APPROVALS

Sunovion Pharmaceuticals, Inc.
Attention: Bridget Walton, MS, RAC
Director, Regulatory Affairs
One Bridge Plaza North, Suite 510
Fort Lee, NJ 07024

Dear Ms. Walton:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received August 31, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Latuda (lurasidone hydrochloride) 20 mg, 40 mg, 80 mg, and 120 mg tablets.

We acknowledge receipt of your amendments dated October 12, 2012, November 21, 2012, February 28, 2013, March 19, 2013, March 20, 2013, March 25, 2013, May 7, 2013, and May 20, 2013.

These "Prior Approval" supplemental new drug applications propose the following additional indications: treatment of patients with depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

We have completed our review of these supplemental applications, as amended. They are 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), 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).

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.

We are waiving the pediatric study requirement for birth to 9 years because necessary studies are impossible or highly impracticable. This is because it is extremely difficult to make a diagnosis of bipolar disorder in children younger than 10 years. Therefore, studies in children younger than 10 years would be highly impractical.

We are deferring submission of your pediatric study for ages 10 to 17 years for this application because adult studies are completed and ready for approval.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act/FDCA are required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act/FDCA. This required study is listed below.

2058-1 A controlled efficacy and safety study of lurasidone in the treatment of pediatric patients (ages 10 to 17 years) with a diagnosis of depressive episode associated with bipolar disorder

Final Protocol Submission:	December 30, 2013
Study/Trial Completion:	December 30, 2015
Final Report Submission:	December 30, 2016

2058-2 A long-term, open-label safety study of study of lurasidone in the treatment of pediatric patients (ages 10 to 17 years) with a diagnosis of depressive episode associated with bipolar disorder

Final Protocol Submission:	December 30, 2013

Study/Trial Completion:	December 30, 2016
Final Report Submission:	December 30, 2017

Submit the protocol(s) to your IND 103427, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

2058-3 A placebo-controlled, randomized withdrawal maintenance study of lurasidone in patients with bipolar I disorder

The timetable you communicated on June 24, 2013, states that you will conduct this study according to the following schedule:

Final Protocol Submission:	May 6, 2013 (We acknowledge that this milestone has been completed)
Study/Trial Completion:	September 30, 2015
Final Report Submission	March 30, 2016

Submit clinical protocols to your IND 103427 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

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/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. 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, please email Ann Sohn, Regulatory Project Manager, at ann.sohn@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
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/

MITCHELL V Mathis
06/28/2013