DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200603

NDA APPROVAL

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

Dear Ms. Walton:

Please refer to your New Drug Application (NDA) dated and received December 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Latuda (lurasidone hydrochloride) 40 mg and 80 mg tablets.

We acknowledge receipt of your amendments dated January 7, 2010, January 26, 2010, February 3, 2010, February 4, 2010, March 4, 2010, March, 30, 2010, April 8, 2010, April 19, 2010, April 20, 2010, April 28, 2010, April 29, 2010, May 10, 2010, May 11, 2010, May 25, 2010, May 27, 2010, June 14, 2010, June 16, 2010, June 29, 2010, July 1, 2010, July 8, 2010, July 19, 2010, July 28, 2010, July 30, 2010, August 3, 2010, August 9, 2010, August 17, 2010, August 26, 2010, September 3, 2010, September 15, 2010, September 17, 2010, October 5, 2010, October 6, 2010, October 7, 2010, October 8, 2010, October 13, 2010, October 14, 2010, October 15, 2010, October 18, 2010, October 21, 2010 and October 26, 2010.

This new drug application provides for the use of Latuda (lurasidone) for the treatment of schizophrenia.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is

identical to 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible via publicly available labeling repositories.

(b) (4)

In addition, we strongly encourage you to develop a 20 mg strength. An alternative would be to score the 40 mg tablet. This lower strength would permit more flexible dosing in certain subgroups, e.g., patients with hepatic or renal impairment, or patients taking moderate 3A4 inhibitors.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 26, 2010, submission containing printed carton and container labels. Submit final printed carton and container labels that are identical to the carton and immediate container labels as agreed upon in our October 27, 2010 communication 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 titled "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 200603**." 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.

PROPRIETARY NAME

The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Psychiatry Products do not object to the use of the proprietary name, Latuda, for this product.

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 ages 0 to 12 years in the treatment of schizophrenia, as studies are highly impractical because of the low incidence of this disease in these age ranges.

We are deferring submission of your pediatric studies for ages 13 to 17 years in the treatment of schizophrenia because this product is ready for approval for use in adults and the pediatric studies have not been completed.

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

1701-1 A deferred pediatric study under PREA for the treatment of schizophrenia in pediatric patients ages 13 to 17 years. A study to obtain pharmacokinetic data and provide information pertinent to dosing of lurasidone tablets in the relevant pediatric population.

Final Protocol Submission Date: by October 30, 2011
Study/Trial Completion Date: by December 31, 2012
Final Report Submission: by October 30, 2015

1701-2 A deferred pediatric study under PREA for the treatment of schizophrenia in pediatric patients ages 13 to 17 years. A study of the efficacy and safety of lurasidone tablets in the relevant pediatric population.

Final Protocol Submission Date: by March 30, 2013
Study/Trial Completion Date: by April 30, 2015
Final Report Submission: by October 30, 2015

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

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of the following postmarketing commitments agreed upon in your communications dated October 21, 2010.

1701-3 To evaluate the longer-term, i.e. maintenance, efficacy of lurasidone in the treatment of adults with schizophrenia. This trial must be placebo-controlled, utilize a randomized withdrawal design, and include an adequate period of stabilization with open-label treatment of lurasidone prior to double-blind randomization.

Final Protocol Submission:	by April 30, 2011
Trial Completion Date:	by October 30, 2014
Final Report Submission:	by October 30, 2015

1701-4 It is not apparent from the trials you have conducted in schizophrenia that the lowest effective dose of lurasidone has been identified. We ask that you further characterize the utilization of lurasidone in the treatment of adults with schizophrenia with a dose lower than 40 mg (e.g. 20 mg daily) through an adequate and well controlled trial.

Final Protocol Submission:	by April 30, 2011
Trial Completion:	by October 30, 2014
Final Report Submission:	by October 30, 2015

Submit clinical protocols to your IND 61292 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all 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, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**".

ADVISORY COMMITTEE

Your application for lurasidone was not referred to an FDA advisory committee because this drug is not the first in its class and the safety profile is similar to that of other drugs approved for this indication.

PROMOTIONAL MATERIALS

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more

information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

Please submit one market package of the drug product when it is available.

DISSOLUTION METHOD AND SPECIFICATIONS

The dissolution method test conditions are as follows:

Parameter	Condition
Apparatus:	USP <711> II (Paddle)
Medium:	McIlvaine's buffer at pH 3.80 ± 0.05 units
Volume:	900 mL
Rotation:	50 rpm ± 2 rpm
Temperature:	37ºC ± 0.5ºC

The dissolution specifications for the 40 and 80 mg dosage strengths should be: Not less than (b) (4) of the labeled amount of lurasidone HCl is dissolved in 20 minutes.

EXPIRY

A 30 month expiry date is granted based on the available stability data.

OTHER

We note your commitment to our request conveyed in FDA Form 483.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

SPECIAL REPORTING REQUIREMENTS FOR ANGIOEDEMA

We note your agreement, in your October 26, 2010 email, to submit all initial and follow-up adverse drug experiences pertaining to angioedema as Postmarketing 15-day "Alert Reports" as defined under 21 CFR 314.80(c).

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm.

POST-ACTION FEEDBACK MEETING

New molecular entities and new biologics qualify for a post-action feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, email Ann Sohn, Regulatory Project Manager, at ann.sohn@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
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/

ROBERT TEMPLE
10/28/2010