DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021476/S-024, S-026

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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

Attention: Helen Milton, Ph.D.
Senior Director, Regulatory Affairs

Dear Dr. Milton:

Please refer to your Supplemental New Drug Applications (sNDA) noted below, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lunesta (eszopiclone) Tablets.

Application	Submitted on:	Received on:	Provides for:
S-024	January 6, 2011	January 6, 2011	"Changes Being Effected" Supplement: PLR conversion
S-026	April 10, 2012	April 10, 2012	"Prior Approval" Supplement: Pediatric Study Requirements

We acknowledge receipt of your amendments to S-024 (PLR conversion) dated February 15, 2011, December 6, 2011, August 3, 2011, and October 5, 2012.

Supplement-024:
This supplement contains changes to the package insert and medication guide in Physician's Labeling Rule (PLR) format.

Supplement-026:
This supplement contains final study reports in fulfillment of the Pediatric Written Request of April 13, 2010.

We have completed our review of supplemental applications **S-024 and S-026** and the supplemental applications are approved, effective on the date of this letter.

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, and Medication Guide), 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 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/COMMITMENT

PMR 1206-2: Pediatric Studies in insomnia associated ADHD in children ages >6 years to <18 years

In addition, we have reviewed your submission and note that you have fulfilled the postmarket pediatric study requirement for ages > 6 years to <18 years for this application.

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 Cathleen Michaloski, BSN, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,
{See appended electronic signature page}
Russell G. Katz, M.D.
Director
Division of Neurology 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/

RUSSELL G KATZ
10/10/2012