DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021476/S-030

SUPPLEMENT APPROVAL

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 Application (sNDA) dated April 18, 2014, received April 18, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lunesta (eszopiclone) 1 mg, 2 mg, and 3 mg tablets.

We acknowledge receipt of your amendment dated April 24, 2014.

We also refer to our letter dated March 19, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Lunesta. This information pertains to the risk of next-day psychomotor impairment, including driving impairment, and to patients not reliably being aware of this impairment.

This supplemental new drug application provides for revisions to the labeling for Lunesta consistent with our letter of March 19, 2014.

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 and with the minor editorial revisions listed below and indicated in the enclosed labeling.

1. Minor edits to cross-referenced sections of the prescribing information
2. Updates to dates in Highlights of the prescribing information

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, except with the revisions indicated, the enclosed labeling (text

for the package insert, 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 via 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 with the revisions indicated above 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).

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, contact Cathleen Michaloski, Sr. Regulatory Project Manager, at Cathleen.michaloski@fda.hhs.gov or by phone at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Billy Dunn, M.D.
Acting 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/

WILLIAM H Dunn
05/15/2014