



NDA 021476/S-021

SUPPLEMENT APPROVAL

Sunovion Pharmaceuticals, Inc.
91 Waterford Dr.
Marlborough, MA 01752-7010

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

Dear Dr. Parthum:

Please refer to your Supplemental New Drug Application (sNDA) dated December 8, 2009, received December 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lunesta, 2 and 3 mg oral Tablets.

We acknowledge receipt of your amendment dated January 6, 2012.

This "Changes Being Effected" supplemental new drug application proposes revisions to the bottle labels and the professional samples.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

Submit final printed carton and container labels that are identical to the enclosed carton and container labels submitted on January 6, 2012, 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021476/S-021.**" Approval of this submission by FDA is not required before the labeling is used.

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, Sr. 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(S):
Carton and Container 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
01/26/2012