



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021782/S-006, (b) (4) S-014

SUPPLEMENT APPROVAL

Takeda Global Research and Development Center, Inc.
One Takeda Parkway
Deerfield, IL 60015-2235

Attention: Kirsten Dale
Manager, Regulatory Affairs Strategy

Dear Ms. Dale:

Please refer to the supplemental new drug applications noted below submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rozerem (ramelteon) Tablets, 8 mg.

Application	Submitted on:	Received on:	Provides for:
S-006	March 30, 2007	April 2, 2007	"Changes Being Effected" Supplement: Container labels
(b) (4)			
S-014	June 18, 2009	June 19, 2009	"Changes Being Effected" Supplement: Professional sample labels

We acknowledge receipt of your submissions dated March 30, 2007 (S-006), (b) (4) and June 18, 2009 (S-014).

These "Changes Being Effected" supplemental new drug applications provide for changes to the container label (S-006) and professional sample card trays (S-014).

We have completed our review of S-006 and S-014 and the supplements are approved, effective the date of this letter, for use as recommended in the enclosed, agreed-upon container labeling.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the enclosed container labels submitted on March 30, 2007 (S-006) and June 18, 2009 (S-014), respectively

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 021782/S-006, and S-014.**” 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, 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):

Container Labeling
Professional sample card trays

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
03/01/2012