



NDA 21782/S-015

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Takeda Global Research & Development Center, Inc.
Attention: Kirsten Dale
Manager, Regulatory Affairs
One Takeda Parkway
Deerfield, Illinois 60015

Dear Ms. Dale:

Please refer to your Supplemental New Drug Application (sNDA) dated June 23, 2011, received June 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rozerem (ramelteon) tablets.

We acknowledge receipt of your amendment dated June 29, 2011 that included a risk evaluation and mitigation strategy (REMS) assessment.

This supplemental new drug application proposes to eliminate the requirement for the approved Rozerem (ramelteon) REMS.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Rozerem (ramelteon) was originally approved on October 20, 2008. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Rozerem (ramelteon).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Rozerem (ramelteon) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Rozerem (ramelteon) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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
08/04/2011