**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-782/S-001

Takeda Global Research & Development Center, Inc.
475 Half Day Road
Lincolnshire, Illinois 60069

Attention: Tracy Lynch
Program Manager, Regulatory Affairs

Dear Ms. Lynch:

Please refer to your supplemental new drug application dated July 28, 2005, received July 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rozerem (ramelteon).

This "Changes Being Effected" supplemental new drug application provides for revised bottle and container labels.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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/s/
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Rigoberto Roca
8/18/2005 05:25:26 PM
for Bob Rappaport, M.D.