DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022196/ S-003

SUPPLEMENT APPROVAL

ECR Pharmaceuticals
P.O. Box 71600
Richmond, Virginia 20705

Attention: Robert G. Ferraino
Director, Regulatory Affairs

Dear Mr. Ferraino:

Please refer to your Supplemental New Drug Application (sNDA) dated August 19, 2010, received August 19, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zolpimist (zolpidem tartrate) 5 mg per Oral Spray.

We acknowledge receipt of your amendment dated September 3, 2010, submitted in response to our August 31, 2010 electronic communication, which contained the first assessment of the Zolpimist risk evaluation and mitigation strategy (REMS) and additional revised REMS documents.

This "Prior Approval" supplemental application provides for proposed modifications to the approved REMS for Zolpimist.

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

In addition, after consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be adequate.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Zolpimist (zolpidem tartrate) was originally approved on December 19, 2008. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of a timetable for submission of assessments revised to include an additional assessment to be completed four years following approval of the REMS.

Your proposed modified REMS, submitted on September 3, 2010 and appended to this letter, is approved.

There are no changes to the REMS assessment plan described in our December 19, 2008 letter.

Assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 022196
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022196 PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022196
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)>>

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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, MPH, 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 – REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CATHLEEN B MICHALOSKI
10/05/2010

RUSSELL G KATZ
10/11/2010