DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22253/S-020
NDA 22254/S-013
NDA 22255/S-007

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

UCB, Inc.
Attention: Susan Tegtmeyer, M.S.
Associate Director, Regulatory Affairs
1950 Lake Park Drive
Smyrna, Georgia 30080

Dear Ms. Tegtmeyer:

Please refer to your Supplemental New Drug Application (sNDA) dated July 13, 2011, received July 13, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vimpat (lacosamide) Tablets, Oral Solution, and Injection.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 26, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Vimpat (lacosamide) 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 Vimpat (lacosamide) was originally approved on October 28, 2008, and the most recent REMS modification was approved on April 20, 2010. 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 Vimpat (lacosamide).

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 Vimpat (lacosamide) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Vimpat (lacosamide) 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 Jacqueline Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160.

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
08/10/2011