



NDA 20712/S-034

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Shire, Inc.
Attention: Linda Mota
Manager, Global Regulatory Affairs
725 Chesterbrook Blvd
Wayne, PA 19087-5637

Dear Ms. Mota:

Please refer to your Supplemental New Drug Application (sNDA) dated June 22, 2011, received June 22, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Carbatrol (carbamazepine) extended-release capsules.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated August 3, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Carbatrol (carbamazepine) extended-release capsules 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 Carbatrol (carbamazepine) extended-release capsules was originally approved on January 26, 2011. 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 Carbatrol (carbamazepine) extended-release capsules.

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 Carbatrol (carbamazepine) extended-release capsules outweigh its risks.

Therefore, we agree with your proposal and a REMS for Carbatrol (carbamazepine) extended-release capsules 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 H. 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
08/22/2011