DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16608/S-106
NDA 18281/S-054
NDA 18927/S-047
NDA 20234/S-039

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Novartis Pharmaceutical Corporation
Attention: Susan Kummerer
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Kummerer:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 19, 2011, received October 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tegretol (carbamazepine) tablets, chewable tablets, oral suspension, and extended-release tablets.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated October 19, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved 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 Tegretol (carbamazepine) was originally approved on March 3, 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 Tegretol (carbamazepine).

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 Tegretol (carbamazepine) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Tegretol (carbamazepine) 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
10/30/2011