DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21014/S-031
NDA 21285/S-025

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 Application (sNDA) dated October 7, 2011, received October 7, 2011, for Trileptal (oxcarbazepine) oral suspension and to your sNDA dated October 10, 2011, received October 11, 2011, for Trileptal (oxcarbazepine) tablets, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessments dated October 7, 2011, for sNDA 21285/S-025, and October 11, 2011, for sNDA 21014/S-031.

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 Trileptal (oxcarbazepine) 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 Trileptal (oxcarbazepine).

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 Trileptal (oxcarbazepine) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Trileptal (oxcarbazepine) 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