



NDA 020646 / S-020

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Cephalon, Inc.
Attention: Paul Kirsch
Senior Director and Group Leader
Regulatory Affairs
PO Box 4011
41 Moores Road
Frazer, PA 19355

Dear Mr. Kirsch:

Please refer to your Supplemental New Drug Application (sNDA) dated December 6, 2011, received December 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gabitril (tiagabine hydrochloride) tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated December 7, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Gabitril (tiagabine hydrochloride) 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 Gabitril (tiagabine hydrochloride) was originally approved on October 11, 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 Gabitril (tiagabine hydrochloride).

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 Gabitril (tiagabine hydrochloride) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Gabitril (tiagabine hydrochloride) 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 Stephanie Parncutt, PharmD, Regulatory Project Manager, at (301) 796-4098.

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
01/25/2012