DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-646/S-014

Cephalon, Inc.
Attention: Carol S. Marchione
Senior Director, Regulatory Affairs
145 Brandywine Parkway
West Chester, PA 19380-4245

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated November 9, 2004, received November 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gabitril (tiagabine hydrochloride) Tablets.

We acknowledge receipt of your submissions dated September 21, 2004, November 19, 2004, and December 21, 2004.

This supplemental new drug application provides for the addition of new safety information to the Gabitril package insert regarding reports of seizures in patients without a prior history of seizures.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-646/S-014**." Approval of this submission by FDA is not required before the labeling is used.

As we agreed, you will send a "Dear Health Care Professional" letter informing health care professionals about the labeling changes pertaining to new onset seizures in non-epilepsy patients. When the letter is issued, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, Pharm.D., Senior Regulatory Project Manager, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
2/14/05 05:27:24 PM