



NDA 20-646/S-015

Cephalon, Inc.
Attention: David Desris, PharmD.
Director, CMC Regulatory Affairs
41 Moores Rd.
P.O. Box 4011
Frazer, PA 19355

Dear Dr. Desris:

Please refer to your supplemental new drug application dated July 29, 2005, received July 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gabitril (tiagabine) tablets.

We acknowledge receipt of your submission dated November 11, 2005.

This supplemental new drug application provides for :

- The use of three new tablet strengths (6 mg, 8 mg and 10 mg) in addition to the currently approved 2 mg, 4 mg, 12 mg and 16 mg tablets.
- An alternate manufacturer of the drug substance (tiagabine HCl monohydrate) and drug product at (b) (4)
- Release and stability testing sites
- Drug product packaging sites
- Several new container/closure systems together with changes in the tablet-count of the containers.
- Modifications to the drug substance and drug product release and stability specifications.
- Modifications to the manufacture of the drug substance and drug product
- Modifications to the analytical techniques for in-process, release and stability testing for the drug substance and drug product.

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 agreed-upon labeling text.

As we have agreed, we have not included any language in the approved labeling referring to the blister packaging because you have not provided information related to the final market presentation, i.e., tablet count, carton labels, and blister labels. We recommend that you submit this information in a CBE-0 labeling supplement.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted July 29, 2005).

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-015** ." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Courtney Calder, Pharm.D., Regulatory Project Manager, at (301) 796-1050.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology 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
11/29/2005 03:12:20 PM