



NDA 20-882

Food and Drug Administration
Rockville MD 20857

Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
Attention: Sean Brennan, Ph.D.
2800 Plymouth Road
Ann Arbor, MI 48105

OCT 9 1998

Dear Dr. Brennan:

Please refer to your new drug application (NDA) dated July 1, 1997, received July 2, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Neurontin (gabapentin) Tablets.

We acknowledge receipt of your submissions dated August 12, 1998, and August 18, 1998. Your submission of August 12, 1998 constituted a full response to our July 1, 1998 action letter. The user fee goal date for this application is October 13, 1998.

This new drug application provides for the use of Neurontin (gabapentin) Tablets for use as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling (package insert submitted August 12, 1998, immediate container and carton labels submitted August 12, 1998) with the revisions listed below. Accordingly, the application is approved effective on the date of this letter.

The biowaiver request for 800 mg tablets may be granted based on established bioequivalence of 600 and 800 mg tablets manufactured on a commercial and pilot scale, respectively, and results of dissolution profiles, compositional proportionality, and solubility of the drug. Please adopt the following dissolution method and specifications:

Apparatus:	II (Paddle)
Speed:	50 rpm
Medium:	900 mL 0.06 N HCL at 37°C
Specification	Not less than (b)(4)(C) dissolved at 45 minutes

The approved expiration date is 24 months for 600 mg tablets, and 12 months for 800 mg tablets.

(b)(4)(TS)
(b)(4)(TS)

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the

product misbranded and an unapproved new drug.

1. In the **DESCRIPTION** section, "NF" should be deleted from the first line of the 3rd paragraph.
2. In the **HOW SUPPLIED** section, the following sentence shall replace the current one under **Storage (Tablets)**:

**Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)
[see USP Controlled Room Temperature]**

3. Please note the changes following the approval letter of September 29, 1998 for NDA 20-235/S-011 Neurontin Capsules. In the **DOSAGE AND ADMINISTRATION** section, the sentences below have been deleted:

Titration to an effective dose can take place rapidly, over a few days, giving 300 mg on Day 1, 300 mg twice a day on Day 2, and 300 mg three times a day on Day 3. To minimize potential side effects, especially somnolence, dizziness, fatigue, and ataxia, the first dose on Day 1 may be administered at bedtime.

To replace the above sentences, the following sentence has been added:

The starting dose is 300 mg three times a day.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-882." Approval of this submission by FDA is not required before the labeling is used.

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

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

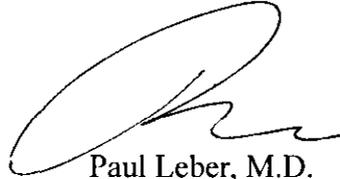
Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, contact Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

A handwritten signature in black ink, appearing to be 'P. Leber', written over a large, light-colored oval shape.

Paul Leber, M.D.

Director

Division of Neuropharmacological Drug Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research