DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-235/S-023
NDA 20-882/S-009
NDA 21-129/S-010

Parke-Davis Pharmaceuticals Limited
c/o Pfizer, Inc.
2800 Plymouth Rd.
P.O. Box 1047
Ann Arbor, MI 48106-1047

Attention: Drusilla Scott, Ph.D.
Director, Regulatory Strategy and Registration
Worldwide Regulatory Affairs

Dear Dr. Scott,

Please refer to your supplemental new drug applications dated January 15, 2002, received January 16, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Neurontin (gabapentin) capsules, Neurontin (gabapentin) tablets, and Neurontin (gabapentin) oral solution.

We also acknowledge receipt of your submissions dated February 11, 2002 and May 28, 2002. These supplemental new drug applications administratively provide for labeling reviewed and approved under NDA 21-397, NDA 21-423, and NDA 21-424.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted May 28, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-235/S-023, 20-882/S-009, 21-129/S-010." Approval of these submissions by FDA is not required before the

labeling is used.

Please note that, during our review of your proposed labeling as compared to the last approved Neurontin labeling (under NDA 21-216, NDA 20-235/S-015, NDA 20-882/S-002, and NDA 21-129/S-005 on October 12, 2000), we found that the word "adult" was omitted in the 1st sentence in the CLINICAL PHARMACOLOGY/Special Populations/Hemodialysis subsection. Specifically, the sentence read " In a study in anuric **adult** subjects (N=11), the apparent elimination half-life of gabapentin on nondialysis days was about 132 hours; dialysis three times a week..." in the last approved Neurontin labeling. We ask that you add the word "adult" back to this sentence at the next printing of the Neurontin package insert.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-2850.

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

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

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