



Food and Drug
Administration
Rockville MD 20857

NDA 20-235/S-022
NDA 20-882/S-008
NDA 21-129/S-009
NDA 21-216/S-001

Pfizer Inc.
Pfizer Pharmaceuticals Group
Attention: Lucy Castro
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Castro:

Please refer to your supplemental new drug applications dated November 8, 2001, received November 9, 2001, 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.

These "Changes Being Effected" supplemental new drug applications provide for an update to the package insert for Neurontin products to reflect the addition of the Pfizer name to the labeling.

We have completed the review of these supplemental applications, 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 final printed labeling submitted November 8, 2001. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about these drug products (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 these NDAs 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 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

**This is a representation of an electronic record that was signed electronically and
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/s/

Russell Katz
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