DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-235/S-029
NDA 20-882/S-015
NDA 21-129/S-016

Pfizer Inc.
Attention: Manini Patel
Director, Worldwide Regulatory Affairs
235 E. 42nd Street
New York, NY 10017

Dear Ms. Patel:

Please refer to your supplemental new drug applications dated August 20, 2003, received August 21, 2003, 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 new safety information and administrative related modifications to the Neurontin package insert.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Please note that the enclosed labeling includes our agreement from January 31, 2005, that the following phrase should be added to the end of the last sentence of the last paragraph in the **Dosage and Administration** section:

"(a longer time period may be needed at the discretion of the prescriber)."

It also includes the previously agreed upon removal of the words "such as dyskinesia" from the last sentence of the first paragraph of the **Postmarketing and Other Experience** subsection of the **ADVERSE REACTIONS** section.

The final printed labeling (FPL) must be identical to, and include the revisions listed, the enclosed labeling text for the package. The above revisions are terms of the approval of these applications.

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 these submissions "**FPL for approved supplement NDA 20-235/S-029, NDA 20-882/S-015, and NDA 21-129/S-016**." Approval of these submissions by FDA is not required before the labeling is used.

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, 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 Courtney R. Calder, Pharm.D., Regulatory Project Manager, at (301) 594-5315.

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
2/18/05 04:36:34 PM