DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-446/S-006

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attn: Robert B. Clark
Vice President, US Regulatory

Dear Mr. Clark:

Please refer to your supplemental new drug application dated April 24, 2006, received April 25, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lyrica (pregabalin) Capsules C-V.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY: In Vitro Studies** section of the package insert to include results of an in-vitro study of the propensity of pregabalin to induce CYP-enzyme metabolism.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the enclosed labeling text for the package insert. The revisions were agreed upon in your October 24, 2006, email communication. These revisions are terms of the approval of this application.

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 21-446/S-006, S-ZZZ**." Approval of this submission 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Lisa Malandro, Regulatory Project Manager, at (301) 796-1251.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

10/27/2006 12:26:38 PM