DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-446/S-002, S-003

Pfizer Inc.
2800 Plymouth Road
Ann Arbor, Michigan 48105

Attention: Jonathan Parker, R.Ph., M.S.
Global Regulatory Leader
Regulatory Strategy
Worldwide Regulatory Affairs

Dear Mr. Parker:

Please refer to your supplemental new drug applications dated August 16 and October 4, 2005, received August 17 and October 4, 2005, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act for Lyrica Capsules.

The "Changes Being Effected" Supplement S-002 is submitted to reflect the scheduling of Lyrica as Cv, under the Controlled Substance Act.

The "Changes Being Effected" Supplement S-003 is submitted to reflect minor editorial changes to the package insert submitted August 17, 2005.

We have completed our review of these supplemental new drug applications, and they are approved, effective on the date of this letter.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 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

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

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