DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-723

Pfizer Global Research and Development
2800 Plymouth Road
Ann Arbor, Michigan 48105

Attention: Jonathan M. Parker, RPh, MS
Global Regulatory Leader, Regulatory Affairs

Dear Mr. Parker:

Please refer to your new drug application (NDA) dated October 30, 2003, received October 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LYRICA™ (pregabalin) Capsules, 25/50/75/100/150/200/225/300 mg.

We acknowledge receipt of your submissions dated November 20, 2003, and January 8, 12, 16, and 30, February 5, 12, 13, 16, 17, 20, 23, 25(3), 26, and 27, March 3, 17, 19, 30, and 31, April 6, 8, 9, 12, 19, 20, 21, 22, and 28, May 3, 4, 13, 17, 18, 19, 25, 26, and 27, June 2, 3, 4, 7, 9, 14, 18, 21, 22, 24, 25, 28, and 29, July 1, 2, 6, 7, 9, 14, 16, 20, 22, 26, and 27, and August 3, 5, 12, 18, 19, 20, 23, 24, and 25, September 3, 7, 8, and 13, October 26, November 1(2) and December 30(2), 2004.

The November 1, 2004, submission constituted a complete response to our August 31, 2004, action letter.

This new drug application provides for the use of LYRICA™ (pregabalin) Capsules for the management of postherpetic neuralgia.

We have completed our review of this application, as amended, 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 to the submitted labeling (text for the package insert and for the patient package insert submitted December 30, 2004). Immediate container and carton labels must be identical to those submitted July 9, 2004, with the addition of the word "Capsules" to the established name as agreed upon in the November 3, 2004, teleconference. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-723**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

The final scheduling of this product under the Controlled Substances Act is currently proceeding, but not yet complete as of the date of this letter. We note your commitment of December 30, 2004, not to market this drug until the scheduling is finalized. We further note that, when finalized, appropriate revisions should be made to the package insert, the patient-package insert and the product labeling through supplementation of your NDA. This would include the statements detailing the scheduling of Lyrica in the labeling, as required under 21 CFR 201.57 (h)(1).

We remind you of your postmarketing study commitments in your submission to NDA 21-446 dated December 30 2004.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anesthetic, Critical Care and Addiction Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field a21-446 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Lisa Malandro, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer

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