



NDA 21-446/S-010

C.P. Pharmaceuticals International C.V.
c/o Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attn: James Bammert, Pharm.D.
Associate Director, Worldwide Regulatory Strategy & Quality Assurance

Dear Dr. Bammert:

Please refer to your supplemental new drug application dated December 20, 2006, received December 21, 2006, 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 January 24 and 26, March 21, April 13 and 19, May 1, 8, 9, 14 (3), 18, and 24, and June 5, 13, 14, 19 and 21, 2007.

This supplemental new drug application provides for the use of LYRICA (pregabalin) Capsules for the management of fibromyalgia.

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.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-446/S-010." In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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 ages 0 to 12 years and deferring pediatric studies for ages 13 to 16 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the management of fibromyalgia in pediatric patients ages 13 to 16.

Final Report Submission: January 31, 2012

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments.**"

We remind you of your postmarketing study commitment in your submission dated June 21, 2007. This commitment is listed below.

2. A single dose, pharmacokinetic, open-label, clinical study in healthy lactating women. Concentrations of pregabalin will be assessed in maternal plasma and breast milk so as to estimate potential infant exposure.

Protocol Submission: by January 31, 2008

Study Start: by January 31, 2009

Final Report Submission: by July 31, 2010

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol,**" "**Postmarketing Study Commitment Final Report,**" or "**Postmarketing Study Commitment Correspondence.**"

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, MBA, Regulatory Health 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
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