DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021446/ S-032
NDA 022488/ S-011

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

PF Prism CV
445 Eastern Point Road
Groton CT 06340

Attention: Lu Zhang, PhD
Senior Director, Worldwide Safety & Regulatory

Dear Dr. Zhang:

Please refer to your supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA	Supplement	Product Name	Date of Submission and Receipt
021446	032	Lyrica (pregabalin) Capsules	February 29, 2016
022488	011	Lyrica (pregabalin) Oral Solution	February 29, 2016

These Prior Approval supplemental new drug applications propose revisions to section **8.4 USE IN SPECIFIC POPULATIONS:** Pediatric Use section of the Package Insert, and to the **Medication Guide**, incorporating the results of the postmarketing requirement (PMR) study, "A 15-week, randomized, double-blind, parallel-group, placebo-controlled flexible-dose safety and efficacy study of pregabalin in adolescents (12 through 17 years old) with fibromyalgia".

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and Medication

Guide, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copies should provide appropriate annotations, including supplement numbers and annual report dates.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated June 15, 2015, containing the final report for the following postmarketing requirements listed in the April 8, 2013, "release from postmarketing requirement/new postmarketing requirement" letter.

NDA 021446/S-010

667- 3 Deferred pediatric study under PREA for the management of fibromyalgia in pediatric patients ages 13 to 17.

Final Report Submission: December 31, 2017

NDA 022488:

1576-5 Deferred pediatric study under PREA, a randomized, double-blind, placebo-controlled study to evaluate the efficacy, pharmacokinetics, and safety of pregabalin in pediatric patients with fibromyalgia ages 13 through 17 years, inclusive.

Final Report Submission: December 31, 2017

We have reviewed your submissions and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the December 30, 2004, and June 10, 2005, approval letters for NDA 021724 and NDA

021446, and the January 4, 2010, approval letter for NDA 022488 and NDA 021446/S-018 that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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 Diana L. Walker, PhD, Senior Regulatory Health Project Manager, at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Ellen Fields, MD, MPH
Deputy Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ELLEN W FIELDS
12/22/2016