DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021446/S-035
NDA 022488/S-013

SUPPLEMENT APPROVAL

PF PRISM CV
c/o Pfizer Inc.
Attention: Mojgan Sadrarhami, PharmD
Senior Director, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Sadrarhami:

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	035	Lyrica (pregabalin) Capsules	November 3, 2017
022488	013	Lyrica (pregabalin) Oral Solution	November 3, 2017

These Prior Approval supplemental new drug applications expand the use of Lyrica as adjunctive therapy in the treatment of partial onset seizures (POS) to include pediatric patients 4 years to 16 years of age.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

Please note that the Agency has previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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 this NDA, 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 copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Fulfilled

The January 4, 2010, approval letter (NDA 22488) includes the following deferred PREA postmarketing requirements:

1576-3: 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 partial onset seizures ages 4 through 16 years, inclusive.

Upon review of these supplemental applications (NDA 021446/S-035 and NDA 022488/S-013), we conclude that the above requirement has been fulfilled.

Partially Addressed

The June 10, 2005 (NDA 21724), and January 4, 2010 (NDA 22488), approval letters include the following deferred PREA postmarketing requirements:

1359-4: Deferred pediatric study under PREA for the treatment of partial onset seizures in pediatric patients ages 1 month [44 weeks gestational age] to 16 years.

1576-4: Deferred pediatric study under PREA, a 12-month open label extension study to evaluate the safety of pregabalin in pediatric patients with partial onset seizures ages 1 month through 16 years, inclusive.

Upon review, we have determined that these supplemental applications (NDA 021446/S-035 and NDA 022488/S-013) partially address the above deferred PREA postmarketing requirements for studies conducted in the age group of 4 to 16 years.

Open

We remind you that there are postmarketing requirements listed in the December 30, 2004 (NDA 21446), June 10, 2005 (NDA 21724), and January 4, 2010 (NDA 22488), approval letters that remain open:

1118-1: Complete an adequate and well-controlled clinical study or studies to better assess the ophthalmologic effects of pregabalin.

1576-2 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 partial onset seizures ages 1 month through 3 years, inclusive.

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, contact Brenda Reggettz, PharmD, Regulatory Health Project Manager, by email at Brenda.Reggettz@fda.hhs.gov or by phone at (240) 402-6220.

Sincerely,

{See appended electronic signature page}

Billy Dunn, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
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/

WILLIAM H Dunn
05/03/2018