NDA 21-446 LYRICA ® (PREGABALIN CAPSULES, USP)

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NDA 22-488 LYRICA ® (PREGABALIN ORAL SOLUTION)

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RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

I. GOAL

The goal of the REMS is to inform patients of the serious risks associated with Lyrica, including the increased risk of suicidal thoughts and behavior.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each Lyrica prescription in accordance with 21 CFR208. The Medication Guide once approved will also be publicly available on Pfizer's web site.

The first method of Medication Guide distribution accompanies package drug product. Each shipment of product will include the USPI and the Medication Guide. The labeling (USPI/Medication Guide) is either glued to the bottle or inserted into the Individual Folding Carton. Once the Medication Guide for Lyrica is approved by FDA, it will accompany the USPI as running text to the USPI and/or will be attached to the bottle or inserted into the carton.

The second method of Medication Guide distribution is independent of medication shipment and is designed to be flexible in order to meet the needs of the dispensing facility. Specifically, to further ensure Medication Guides are provided in sufficient numbers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription, we plan to use the mechanism of distribution used for other widely-prescribed Pfizer products. Pfizer contracts with a third-party fulfillment group responsible for the following activities: identification of all pharmacies/dispensers in the US, timely printing of Medication Guide tear pads, timely shipment of the tear pads (3 pads of 50 per pad), and timely fulfillment of re-ordering of the Medication Guide tear pads in quantities to meet the needs of each dispenser, as specified by the dispenser. There are no limits on the number of Medication Guides a dispenser can request and receive.

All pharmacies/dispensers in the US (approx 80,000) are included in distribution of the tear-pads, including institutional pharmacies (e.g., hospital pharmacies) regardless of the amount of product ordered. Therefore, pharmacies using the Hospital Unit Dose (HUD) will also receive tear pads, in addition to the labeling that accompanies the package. The professional samples packaging (21 and 14 capsule counts) are designed as single unit of use as professional samples only, so the patient receiving these bottles will receive the labeling (including Medication Guide) that is attached to the bottle. Please see appended Medication Guide.

B. Communication Plan

Not applicable.

C. Elements to Assure Safe Use

Not applicable.

D. Implementation System

Not applicable.

E. Timetable for Submission of Assessments

REMS Assessments for Lyrica (Capsules and Oral Solution) will be submitted to FDA 18 months, 3 years, and 7 years following REMS original approval of 23 April, 2009. Pfizer will submit the assessments within 60 days of the closure of the intervals.