

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-509

REMS

LAMICTAL (lamotrigine) XR (Extended Release Tablets)

Drug Class: Anticonvulsant

Applicant Name: SmithKline Beecham d/b/a GlaxoSmithKline

Applicant Address: One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

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

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each LAMICTAL prescription.

- LAMICTAL XR is packaged as a single unit of use and a Medication Guide will be attached to each package. Each Medication Guide is barcode scanned to ensure that the correct version is being used and that the component is available for attaching to each package.

The label of each container or package of LAMICTAL will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and state how the Medication Guide is provided.

Please see the appended Medication Guide.

B. Communication Plan

Not applicable.

C. Elements to Assure Safe Use

Not applicable.

D. Implementation System

Not applicable.

III. Timetable for Submission of Assessments

GlaxoSmithKline will submit REMS assessments to FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. GlaxoSmithKline will submit each assessment so that it will be received by the FDA on or before the due date.