CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022255Orig1s000

REMS

VIMPAT® (lacosamide) Risk Evaluation and Mitigation Strategy (REMS)

NDA 022255 VIMPAT® (lacosamide) oral solution CV
NDA 022253 VIMPAT® (lacosamide) tablets CV
NDA 022254 VIMPAT® (lacosamide) injection CV

Antiepileptic Drug

Schwarz Biosciences, Inc., a member of the UCB Group of Companies
1950 Lake Park Drive, Smyrna, GA 30080

1 GOAL

The goal of this REMS is to communicate the risks of VIMPAT.

2 REMS ELEMENTS

2.1. Medication Guide

A Medication Guide will be dispensed with each VIMPAT prescription. UCB will assure that Medication Guides are provided with each order in sufficient quantity to assure that a Medication Guide is available at the time of dispensing to the patient. As printed materials, Medication Guides will be controlled using appropriate techniques (i.e. barcoding) to assure that the correct Medication Guide is provided with each product order that UCB fills.

The container labeling for the product will contain prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the product is dispensed. In addition, the Medication Guide will be publicly available on the VIMPAT product website, www.vimpat.com.

2.2. Communication Plan

The VIMPAT REMS does not include a Communication Plan.

2.3. Elements to Assure Safe Use

The VIMPAT REMS does not include Elements to Assure Safe Use.

2.4. Implementation System

The VIMPAT REMS does not include Elements to Assure Safe Use, therefore no Implementation System is required.

2.5. Timetable for Submission of REMS Assessments

The Sponsor will submit REMS assessments to the FDA 18 months, 3 years, and 7 years from the date of original approval of the REMS (28 April 2010, 28 October 2011 and 28 October 2015, respectively). 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. UCB will submit each assessment so that it will be received by the FDA on or before the due date.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22255	ORIG-1	SCHWARZ BIOSCIENCES INC	VIMPAT
NDA-22253	SUPPL-6	SCHWARZ BIOSCIENCES INC	VIMPAT
NDA-22254	SUPPL-3	SCHWARZ BIOSCIENCES INC	VIMPAT

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/s/

RUSSELL G KATZ
04/20/2010