NDA 21-710 EQUETRO® (carbamazepine)

Extended-Release Capsules

Antiepileptic Drug Class

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of EQUETRO® (carbamazepine).

II. REMS ELEMENTS:

A. Medication Guide

In accordance with 21 CFR 208.24, Validus Pharmaceuticals, LLC will ensure a currently approved Medication Guide is available for distribution to be dispensed to each patient with an EQUETRO (carbamazepine) prescription.

Sufficient Medication Guides will be included in cartons of EQUETRO (36 bottles) that will be sent to the primary distributors. Instructions to authorized dispensers will specify that enough MG's will accompany each shipment in order to have a sufficient amount for pharmacists to include in every prescription thus complying with 21 CFR 208.24 (e).

In accordance with 21 CFR 208.24(d), Validus will include a statement on the Equetro carton/container labels to alert the authorized dispenser to provide a Medication Guide to each patient to whom the drug is dispensed. Each carton/container will be labeled: "Dispense the accompanying Medication Guide to each patient."

B. Timetable for Submission of Assessments

Validus Pharmaceutical, LLC will submit REMS Assessment 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. Validus will submit each assessment so it will be received by the FDA on or before the due date.