CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022544Orig1s000

REMS

NDA 22-544

GRALISE™ (gabapentin) Tablets

Product Class: Antiepileptic Drug (AED)

Abbott Products, Inc.
901 Sawyer Road
Marietta, GA 30062
January 24, 2011

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 **GRALISE (gabapentin) Tablets** .

II. REMS ELEMENTS

A. Medication Guide

Abbott will ensure that a currently approved Medication Guide is dispensed with each **GRALISE (gabapentin) Tablets** prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Abbott 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. Abbott will submit each assessment so that it will be received by FDA on or before the due date.