RISK EVALUATION AND MITIGATION STRATEGY (REMS) OVERVIEW

I. GOAL

The goal of the REMS is to effectively communicate to patients the risks involved with Edluar.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide (MG) will be dispensed with each Edluar prescription.

Edluar (zolpidem tartrate) sublingual 5 mg and 10 mg tablets are supplied in blister cards (10 tablets per card), in cartons of 10 tablets (1 card per carton), 30 tablets (3 cards per carton), and in cartons of 100 tablets (10 cards per carton). Edluar is packaged as a single unit of use. Based on the assumption that a pharmacist could dispense 1 prescription from a single carton of 10 tablets, 3 prescriptions from a single carton of 30 tablets and 10 prescriptions from a single carton of 100 tablets, 1, 3 and 10 copies of the MG, respectively, will be included in every carton by the sponsor at the time of manufacture/packaging. The MG will also be available at www.TRADENAME.com.

B. Communication Plan

The REMS for Edluar does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for Edluar does not include elements to assure safe use.

D. Implementation System

Because this REMS for zolpidem tartrate sublingual tablets does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The Edular REMS Program will be assessed 18 months, 3 years and 7 years following REMS approval and implementation of the new MG and labeling. The assessment interval period will be no earlier than 60 days prior to the date the respective assessment is due.

A Knowledge, Attitude, and Behavior (KAB) Survey will be developed and field-tested using a battery of selected questions that will ascertain the patients' understanding of the serious risks of zolpidem tartrate sublingual tablets. Once an adequate sample size is obtained, the results will be used to determine the effectiveness of the REMS. The sponsor will evaluate various approaches

to identify and reach appropriate patients while maintaining compliance with HIPAA. The KAB Survey will also be used to evaluate whether the patient or caregiver recalls receiving the printed MG.