INITIAL REMS APPROVAL: 03/2009

MOST RECENT MODIFICATION: 12/2010

NDA 021997
EDLUAR™ (ZOLPIDEM TARTRATE, SL)

SEDATIVE HYPNOTIC

MEDA PHARMACEUTICALS
265 DAVIDSON AVENUE, SUITE 300
SOMERSET, NJ 08873

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

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

2. REMS ELEMENTS:

2.1. Medication Guide

A Medication Guide (MG) will be dispensed with each Edluar sublingual tablet prescription. Edluar sublingual 5 mg and 10 mg tablets are supplied in blister cards (10 tablets per card) in cartons of 30 tablets (3 cards per carton). Three copies of the MG are included in every carton by the sponsor at the time of manufacture/packaging. The MG will also be available at www.edluar.com

2.2. Communication Plan

The REMS for Edluar does not include a Communication Plan.

2.3. Elements to Assure Safe Use

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

2.4. Implementation System

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

2.5. Timetable for Submission of Assessments

Meda submits an assessment of the Edluar REMS for analysis at 18 months, 3 years and 7 years from approval. In addition, a separate assessment, which will include patient survey results, will be submitted by June 11, 2011 (This date is based on an FDA action date of December 11, 2010 for Meda's June 11, 2010 REMS submission).

Table 1: Timetable for Submission of Assessments

Assessment	**Month/Year of Submission**
1st Assessment (18 months from approval)	September 13, 2010
Interim Assessment with Patient KAB	June 11, 2011
2nd Assessment (3 years from approval)	March 13, 2012
3rd Assessment (7 years from approval)	March 13, 2017

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 Edluar. Once an adequate sample size is obtained, the results will be used to determine if 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.