

NDA 21-911__BANZEL™ ((rufinamide, 200 mg and 400 mg tablets))

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

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

II. REMS ELEMENTS

A. Medication Guide

A copy of the current Medication Guide will be printed by the pharmacy and will accompany every dispensed prescription for BANZEL.

Because the Medication Guide is to be included with each prescription dispensed for BANZEL, Eisai has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

B. Communication Plan

The REMS for BANZEL does not include a Communication Plan.

C. Elements to Assure Safe Use

This REMS for BANZEL does not include elements to assure safe use.

D. Implementation System

Because the REMS for BANZEL does not include elements to assure safe use, an implementation system is not required.

III. Assessment of REMS

The timetable for Assessments is as follows:

1st FDAAA assessment: May 2010 (18 months from approval)

2nd FDAAA assessment: November 2011 (3 years from approval)

3rd FDAAA assessment: November 2015 (7 years from approval)

Eisai Inc. will submit the assessments within 60 days of the close of the intervals as noted above.