DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021911/S-008
NDA 201367/S-001

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Eisai, Inc.
Attention: Ira Do, PharmD
Senior Manager, Regulatory Affairs
300 Tice Boulevard
Woodcliff Lake, NJ 07667

Dear Dr. Do:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 13, 2011, received April 13, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Banzel (rufinamide) oral tablets and solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 13, 2011.

These supplemental new drug applications propose elimination of the requirement for the approved REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Banzel (rufinamide) was originally approved on November 14, 2008, and the most recent REMS modification was approved on March 3, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Banzel (rufinamide).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS, and a REMS is no longer necessary to ensure that the benefits of Banzel (rufinamide) outweigh its risks. Therefore, we agree with your proposal, and a REMS for Banzel (rufinamide) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline H. Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
06/01/2011