DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-911/S-004 **SUPPLEMENT APPROVAL**

Eisai Medical Research, Inc.
Attention: Ira Do, Pharm.D.
Senior Manager, Regulatory Affairs
300 Tice Boulevard
Woodcliff Lake, NJ 07677

Dear Dr. Do:

Please refer to your supplemental new drug application dated April 22, 2009, received April 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Banzel (rufinamide) Tablets, 200 and 400 mg.

This "Prior Approval" supplemental new drug application provides for addition of the statement, "ATTENTION: Dispense with Medication Guide provided with this carton" for the 200 mg strength tablets [bottles of 4 (professional sample) and 30 tablets] and the 400 mg strength tablets [bottles of 14 (professional sample) and 120 tablets].

We have completed our review of this application and it is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-911/S-004**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21911	SUPPL-4	EISAI MEDICAL RESEARCH INC	BANZEL ORAL TABS

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
10/16/2009