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APPLICATION NUMBER:

201367Orig1s000

SUMMARY REVIEW

MEMORANDUM

DATE: March 3, 2011

FROM: Director
Division of Neurology Products/HFD-120

TO: File, NDA 201-367

SUBJECT: Action Memo for NDA 201-367, for the use of Banzel (rufinamide) oral suspension 40 mg/mL

NDA 201-367, for the use of Banzel (rufinamide) oral suspension 40 mg/mL, was submitted by Eisai Inc., on 4/30/10. Banzel Tablets are currently approved for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in patients 4 years old and older. This application proposes a new oral suspension formulation. The application contains the results of a bioequivalence (BE) study comparing several different oral suspensions (including the one proposed for marketing) to the approved 400 mg tablet, as well as the requisite chemistry and manufacturing controls (CMC) information. The BE study demonstrated that the to-be-marketed oral suspension is bioequivalent to the approved tablet.

In addition, because there is a Risk Evaluation and Mitigation Strategy (REMS) in place for Banzel Tablets, the sponsor has submitted a REMS amendment, to include the new formulation. The application also contains proposed product labeling, as well as a revised Medication Guide (to include the new suspension), and an Information for Use (IFU) sheet, which describes how the product is to be administered.

(b) (4)

As a result, the sponsor proposed to package the product with 2, 20 cc syringes. These have been found to be able to accurately deliver all doses in the recommended range. In addition, the syringes have been shown to withstand multiple washings. That is, after 90 days of daily washing in a dishwasher, the syringe plunger still functions well, and the mL markings on the outside of the syringe are still clearly visible.

The application has been reviewed by Dr. Steven Dinsmore, medical officer, Dr. Vaneeta Tandon, Office of Clinical Pharmacology, Cathy Miller, Division of Medication Error Prevention and Analysis (DMEPA), Mary Dempsey, Robin Duer, and Melissa Hulett, Division of Risk Management (DRISK), Dr. Quynh-Van

Tran, Division of Drug Marketing, Advertising, and Communications (DDMAC), Dr. Vinayak B. Pawar, Office of Pharmaceutical Sciences (OPS), Kendra Biddick, Office of Compliance, Drs. Abhijit Raha and Martin Yau, Division of Scientific Investigations, Dr. Akm Khairuzzaman, Office of New Drug Quality Assessment, Dr. Norman Hershkowitz, neurology team leader, and Dr. Angela Men, Cross-Discipline Team Leader.

The review team recommends that the application be approved.

I agree. There are no outstanding issues that would preclude approval, and we have agreed with the sponsor that product labeling is acceptable.

For these reasons, then, I will issue the attached Approval letter with appended agree-upon product labeling.

Russell Katz, M.D.

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
03/03/2011