NDA 201367/S-011

APPROVAL LETTER

Eisai Inc.
Attention: Michael Theil
Senior Director, CMC Regulatory Affairs
200 Metro Blvd.
Nutley, NJ 07110

Dear Mr. Theil:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 30, 2022, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Banzel (rufinamide) oral suspension.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

- The addition of (b) (4) as a new manufacturer of the 20-mL oral dosing syringe and of the press-in-bottle adapter for Banzel Oral Suspension along with an associated minor update to the "Instructions for Use" section of the "United States Prescribing Information" (USPI)

- The addition of a descriptive phrase regarding the appearance of the drug product to Section "3 DOSAGE FORMS AND STRENGTHS" of the USPI

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is **approved**, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, instructions for use, and Medication Guide) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Onyekachukwu (Onyeka) Ihezie, PharmD, Regulatory Business Process Manager, at (240) 402 - 2480.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling – USPI, Medication Guide and Patient Instructions for use

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 5/30/2023 11:27:18AM
GUID: 5135f2ad000117842392c50c36c7f28a