NDA 022416/S-021

APPROVAL LETTER

Sumitomo Pharma America, Inc.
Attention: Noriko Deguchi
Associate Director, Global Regulatory Affairs
84 Waterford Drive
Marlborough, MA 01752

Dear Ms. Deguchi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 20, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aptiom (eslicarbazepine acetate) tablet.

This Prior Approval supplemental new drug application provides for the following changes:

- Addition of (b) (4) (b) (4) as an alternate manufacturer of bulk APTIOM Tablets (200 mg, 400 mg, 600 mg, and 800 mg strength) and as an alternate primary drug product packaging site for the bottles.
- Minor manufacturing process changes (b) (4) (b) (4)
- Addition of (b) (4) as an alternate supplier of the (b) (4) (b) (4) bottles.

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.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on February 20, 2024, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final**

Printed Carton and Container Labels for approved NDA 022416/S-021." Approval of this submission by FDA is not required before the labeling is used.

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, please contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs,gov.

Sincerely,

{See appended electronic signature page}

Joyce Crich, Ph.D.
Senior Pharmaceutical Quality Assessor
on Behalf of

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Joyce Crich

Digitally signed by Joyce Crich
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