DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22416/S-011

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENTS

Sunovion Pharmaceutical Inc.
Attention: Kimberly Parthum, Ph.D.
Director, Global Regulatory Affairs
84 Waterford Drive
Marlborough, MA 01752

Dear Dr. Parthum:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on May 15, 2018, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aptiom (eslicarbazepine acetate) tablets, 200 mg, 400 mg, 600 mg, and 800 mg.

This Prior Approval supplemental new drug application provides for the addition of information regarding physical dependence or withdrawal syndrome after abrupt withdrawal to the Drug Abuse and Dependence section of the Aptiom Prescribing Information.

APPROVAL & LABELING

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

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 package insert), 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 from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated May 15, 2018, reporting on the following postmarketing requirement listed in our November 8, 2013, approval letter for NDA 22416:

2099-11	A prospective human physical dependence trial in healthy volunteers in which subjects are titrated to 800 mg of eslicarbazepine acetate and maintained at this dose for four weeks. At the end of the treatment, the drug should be abruptly withdrawn. Withdrawal should be conducted in an inpatient setting with immediate access to physicians capable of managing medical emergencies (e.g., status epilepticus, cardiopulmonary arrest). Withdrawal questionnaires should be administered at the pre-treatment visit, within the last two days of treatment, on the first day post-treatment, on the fourth to fifth day post-treatment, on the tenth to eleventh day post-treatment, and on the twentieth to twenty-first day posttreatment. All adverse events occurring during the withdrawal period are to be collected. Plasma levels of eslicarbazepine should be measured and accompany every administration of withdrawal questionnaires through the fifth day posttreatment.

We have reviewed your submission and have concluded that the above requirement has been fulfilled.

Please note that all of your pediatric assessments required under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c) have not yet been fulfilled. Additional labeling changes may be deferred until results from your required pediatric clinical safety and efficacy studies have been reviewed.

We remind you that there are postmarketing requirements listed in the November 8, 2013, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 LaShawn Dianat PharmD, Regulatory Project Manager, at (240) 402-7713.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ERIC P BASTINGS
03/15/2019 12:48:07 PM