CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

207958Orig1s000

Trade Name: SPRITAM 250 mg, 500 mg, 750 mg, and 1000 mg tablets, for oral use

Generic Name: Levetiracetam

Sponsor: Aprecia Pharmaceuticals Company

Approval Date: July 31, 2015

Indication: For oral use, in the adjunctive therapy treatment of:

- Partial onset seizures in patients with epilepsy 4 years of age and older weighing more than 20 kg

- Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy

- Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207958

NDA APPROVAL

Aprecia Pharmaceuticals Company
89 Twin Rivers Drive
East Windsor, NJ, 08520

Attention: Sanjay Sehgal, Ph.D.
Vice President, Regulatory Affairs and Conformance

Dear Dr. Sehgal:

Please refer to your New Drug Application (NDA) dated October 1, 2014, received October 1, 2014, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for SPRITAM (levetiracetam), 250 mg, 500 mg, 750 mg, and 1000 mg tablets, for oral use.

We acknowledge receipt of your amendments dated:

October 9, 2014	April 13, 2015	June 15, 2015
November 12, 2014	April 21, 2015	June 16, 2015
December 1, 2014	April 29, 2015	June 22, 2015
December 11, 2104	May 1, 2015	July 2, 2015
December 19, 2014	May 8, 2015	July 20, 2015
December 30, 2014	May 18, 2015	July 27, 2015
January 8, 2015	May 28, 2015	July 28, 2015
February 27, 2015	May 29, 2015	July 30, 2015 (3)
March 27, 2015	June 3, 2015	

This new drug application provides for the use of SPRITAM (levetiracetam), 250 mg, 500 mg, 750 mg, and 1000 mg tablets, for oral use, in the adjunctive therapy treatment of:

- Partial onset seizures in patients with epilepsy 4 years of age and older weighing more than 20 kg;
- Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy; and
- Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

We have completed our review of this application, as amended. 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, and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry "*SPL Standard for Content of Labeling Technical Qs and As"* available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* 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 207958**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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, contact Cathy Michaloski, Sr. Regulatory Project Manager, at Cathleen.michaloski@fda.hhs.gov or by phone at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Billy Dunn, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILLIAM H Dunn
07/31/2015