DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207958/S-002

SUPPLEMENT 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 Supplemental New Drug Application (sNDA) dated and received November 19, 2015, 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, oral suspension.

We acknowledge receipt of your amendments dated, December 28, 2015, January 8, 2016, and January 29, 2016.

The "Changes Being Effected" (CBE) supplemental new drug application provides for the change to the product dosage form designation, from oral tablets to oral suspension with subsequent changes to the Prescribing Information, Medication Guide and carton and container labeling, as appropriate.

APPROVAL & LABELING

We have completed our review of the supplemental application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. As per your agreement by email (1/27/16) at the printing of the next commercial carton labeling, the following change will be made:

Carton Labeling Commercial and Professional Sample:

To improve clarity, we recommend use of the word "disintegrate" in place of the word "disperse" and the word "swallowing" in place of the word "administration" in the alternate administration statement on the back panel to be consistent with the patient friendly language used within the Medication Guide. Suggested revision:

"Alternately, add whole SPRITAM tablet(s) to a small volume of liquid in a cup (one tablespoon or enough to cover the medicine); allow the tablet(s) to disintegrate prior to

swallowing. If there is any medicine left in the cup, add a small volume of liquid to the cup, swirl gently, and swallow the liquid."

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, 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 Q's and A's" 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 these NDAs, 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 these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, 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).

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 Cathy Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
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/

ERIC P BASTINGS
02/01/2016