DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 204857

ANDA APPROVAL

Amneal Pharmaceuticals
85 Adams Avenue
Hauppauge, New York 11788
Attention: Alpesh Patel
Vice President-Global Regulatory Affairs

Dear Sir:

This is in reference to your Abbreviated New Drug Application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg.

Reference is also made to the tentative approval letter issued by this office on April 30, 2015, and to your amendments dated April 28 and July 28, 2016.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Vimpat Tablets, 50 mg, 100 mg, 150 mg, and 200 mg of UCB, Inc. (UCB).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, UCB's Vimpat Tablets, 50 mg, 100 mg, 150 mg, and 200 mg, is subject to a period of patent protection. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No RE38,551 (the '551 patent) scheduled to expire on March 17, 2022.

With respect to the '551 patent insofar as it pertains to U-1566 (method of treating, as monotherapy, partial-onset seizures in a patient with epilepsy aged 17 years and older, only) and U-1567 (method of treating, as initial loading dose for monotherapy or adjunctive therapy, partial onset-seizures in a patient with epilepsy aged 17 years or older), your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this a method-of-use patent that does not claim any indication for which you are seeking approval under your ANDA.

With respect to the '551 patent, excluding U-1566 (method of treating, as monotherapy, partial-onset seizures in a patient with epilepsy aged 17 years and older, only) and U-1567 (method of treating, as initial loading dose for monotherapy or adjunctive therapy, partial-onset seizures in a

patient with epilepsy aged 17 years or older), your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg, under this ANDA. You have notified the agency that Amneal Pharmaceuticals (Amneal) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that that litigation was initiated within the statutory 45-day period against Amneal for infringement of the '551 patent in the United States District Court for the District of Delaware [UCB, Inc., UCB Pharma GmbH, Research Corporation Technologies, Inc. and Harris FRC Corporation v. Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co., India Private Limited, Civil Action No. 1:13-cv-01208-UNA]. Although litigation remains ongoing, the 7½ year period identified in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Amneal was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg. Therefore, with this approval, Amneal may be eligible for 180 days of shared generic drug exclusivity for Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg. The Agency notes that Amneal failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Amneal's eligibility for 180-day generic drug exclusivity.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Lacosamide Tablets, 50 mg, 100 mg, 150 mg, and 200 mg.[1] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

Under section 506A of FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

[1] See also Letter to Applicant fr. G. Buehler, Director, Office of Generic Drugs (regarding potential eligibility for 180-day exclusivity for Nateglinide Tablets, 60 mg and 120 mg). This correspondence is currently available on FDA's website at http://www fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM182134.pdf.

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. 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

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 also submit final promotional materials and package insert(s), 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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is

identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs and Master Files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

CAPT Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

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