NDA 214273

NDA APPROVAL

Azurity Pharmaceuticals, Inc.
Attention: Korie Osborn
Vice President, Regulatory Affairs
13160 Foster Street, Suite 190
Overland Park, KS 66213

Dear Ms. Osborn:

Please refer to your new drug application (NDA) dated July 28, 2020, received July 29, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zonisade (zonisamide oral suspension) 100 mg/5 mL.

We acknowledge receipt of your amendment dated January 18, 2022, which constituted a complete response to our May 28, 2021, action letter.

This NDA provides for the use of Zonisade for adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older.

APPROVAL & LABELING

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.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) 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 *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on June 17, 2022, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 "**Final Printed Carton and Container Labeling for approved NDA 214273**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Zonisade shall be 24 months from the date of manufacture when stored at 20°C to 25°C.

ADVISORY COMMITTEE

Your application for Zonisade was not referred to an FDA advisory committee because this drug is not the first in its class.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 1 month because necessary studies are impossible or highly impracticable due to difficulties in diagnostic certainty in this age group and a small amount of available subjects.

We are deferring submission of your pediatric studies for ages 1 month to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

4302-1 A study to evaluate the pharmacokinetics, safety, and tolerability of zonisamide oral suspension to determine a dosing regimen as therapy for partial-onset seizures in children 1 month to 17 years of age that provides drug exposures that are similar to the exposures that are effective in adult patients with partial-onset seizures. The efficacy of zonisamide in children 1 month to 17 years of age for treatment of partial-onset seizures will be addressed by a pharmacokinetic analysis to determine pediatric dosing that will match exposures in children to those in adults. This analysis will require pharmacokinetic data from studies of both adult and pediatric patients (1 month to 17 years of age).

Draft Protocol Submission:	10/2022
Final Protocol Submission:	01/2023
Study Completion:	01/2024
Final Report Submission:	04/2024

4302-2 Long-term open-label safety study of zonisamide oral suspension in children 1 month to 17 years of age (at dosing levels found to be therapeutic) in the treatment of partial-onset seizures. Routine safety measures should be monitored and the study population must include an appropriate representation of age distributions as shown below. Behavioral and cognitive endpoints should be included. At least 15% of the study population should be in each of the following age brackets:

1. 1 month to less than 2 years
2. 2 years to less than 4 years
3. 4 years to less than 8 years
4. 8 years to less than 12 years
5. 12 years to 17 years

Draft Protocol Submission:	12/2023
Final Protocol Submission:	02/2024
Study Completion:	02/2027
Final Report Submission:	06/2027

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your PIND 142839, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

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 Josephine Little, Regulatory Project Manager, via email at Josephine.Little@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nick Kozauer, MD
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

NICHOLAS A KOZAUER
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