NDA 218754

NDA APPROVAL

Azurity Pharmaceuticals, Inc.
Attention: Devaraju Adumekala
Senior Manager, Regulatory Affairs
8 Cabot Road
Suite 2000
Woburn, MA 01801

Dear Devaraju Adumekala:

Please refer to your new drug application (NDA) received September 28, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aprepitant Injectable Emulsion.

We acknowledge receipt of your amendment dated December 19, 2025, following our July 25, 2024, tentative approval letter.

This NDA provides for the use of Aprepitant Injectable Emulsion for the following indications:

In adults, in combination with other antiemetic agents, for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen.
- nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Updated the revision date in Highlights of the Prescribing Information and approved date in the Patient Package Insert to the approval date.

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, Patient Package Insert) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on May 22, 2026, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 218754**." 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 Aprepitant Injectable Emulsion shall be 24 months from the date of manufacture when stored at 2°C to 8°C.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)

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

[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.

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.

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. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

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.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.[5]

THERAPEUTIC EQUIVALENCE EVALUATION REQUEST

Your submission includes a Therapeutic Equivalence Evaluation Request (TEER) submitted pursuant to section 505(j)(7)(A)(v)(I)(aa) of the FD&C Act. Section

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[5] https://www.uspnf.com/

505(j)(7)(A) of the FD&C Act was amended by section 3222 of the Food and Drug Omnibus Reform Act of 2022 (FDORA, enacted December 29, 2022) and, as amended sets forth certain conditions under which FDA evaluates whether an eligible drug submitted in an application pursuant to section 505(b)(2) of the FD&C Act is therapeutically equivalent (TE) to a listed drug relied upon in the 505(b)(2) application. This provision provides that evaluation of requests that meet applicable requirements will be made at the time of approval or not later than 180 days after the date of approval of such application.

We acknowledge your request for a therapeutic equivalence evaluation, and we continue to consider this request. Neither this letter, nor the approval of your application constitutes a determination that your request meets applicable requirements under section 505(j)(7)(A)(v)(I)(aa) of the FD&C Act.

If you have any questions, contact Mary Chung, Regulatory Project Manager, at (301) 796-0260 or Mary.Chung@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Erica Lyons, M.D.
Associate Director for Therapeutic Review
Division of Gastroenterology
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

JOYCE A KORVICK
06/16/2026 10:00:17 AM
Signing on behalf of Erica Lyons