CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

213593Orig1s000

Trade Name:	KONVOMEP
Generic or Proper Name:	omeprazole and sodium bicarbonate for oral suspension
Sponsor:	Azurity Pharmaceuticals, Inc.
Approval Date:	August 30, 2022
Indication:	For the treatment of: • short-term treatment (4 to 8 weeks) of active benign gastric ulcer. • reduction of risk of upper gastrointestinal bleeding in critically ill adult patients.

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213593Orig1s000

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 213593/Original 1

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 and received March 30, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Konvomep (omeprazole and sodium bicarbonate for oral suspension).

We acknowledge receipt of your amendment dated March 4, 2022, which constituted a complete response to our January 30, 2021, action letter.

NDA 213593 provides for the use of Konvomep (omeprazole and sodium bicarbonate for oral suspension) for the following indications which, for administrative purposes, we have designated as follows:

NDA 213593/Original 1 – 40 mg

- short-term treatment (4 to 8 weeks) of active benign gastric ulcer.
- reduction of risk of upper gastrointestinal bleeding in critically ill adult patients.

(b) (4)

The subject of this action letter is NDA 213593/Original 1. [redacted] (b) (4)
(b) (4)

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.

We note that your August 30, 2022, submission includes final printed labeling (FPL) for your Prescribing Information and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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, Instructions for Use, 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.

CARTON AND CONTAINER LABELING

We acknowledge your August 17, 2022, submission containing final printed carton and container labeling.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Konvomep (omeprazole and sodium bicarbonate for oral suspension) shall be 24 months from the date of manufacture of either the bottle of omeprazole, USP or the bottle of diluent for reconstitution of Konvomep containing sodium bicarbonate, USP, whichever is earlier, when stored at refrigerated conditions, 2°C to 8°C (36°F to 46°F). The reconstituted suspension of Konvomep can be stored up to 30 days at refrigerated conditions, 2°C to 8°C (36°F to 46°F).

[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.

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.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 Jay Fajiculay, PharmD, Senior Regulatory Health Project Manager, at (301) 796-9007 or email at jay.fajiculay@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Erica Lyons, MD
Associate Director for Therapeutic Review
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

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

ERICA M LYONS
08/30/2022 03:56:48 PM