CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

210274Orig1s000

Trade Name:	Vancomycin Hydrochloridefor injection, for intravenous use or oral use.
Generic or Proper Name:	Vancomycin Hydrochloride
Sponsor:	Zhejiang Novus Pharmaceuticals Co. Ltd
Approval Date:	January 20, 2023

Indication:

Vancomycin Hydrochloride for Injection is a glycopeptide antibacterial indicated in adult and pediatric patients less than 18 years of age as follows:

- Vancomycin Hydrochloride for Injection administered intravenously is indicated for the treatment of:
  - Septicemia
  - Infective Endocarditis
  - Skin and Skin Structure Infections
  - Bone Infections
  - Lower Respiratory Tract Infections
- Vancomycin Hydrochloride for Injection administered orally is indicated for the treatment of:
  - Clostridioides difficile-associated diarrhea
  - Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains)

Limitations of Use

- Vancomycin Hydrochloride for Injection administered intravenously is not approved for the treatment of C. difficile-associated diarrhea and enterocolitis caused by susceptible isolates of Staphylococcus aureus because it is not effective.
- Vancomycin Hydrochloride for Injection administered orally is not approved for the treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections and lower respiratory tract infections because it is not effective.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Injection and other antibacterial drugs, Vancomycin Hydrochloride for Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

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APPROVAL LETTER

NDA 210274

NDA APPROVAL

Zhejiang Novus Pharmaceuticals Co. Ltd.
c/o NSF Health Sciences
Attention: Andy Papas, PhD, MBA
Vice President
2001 Pennsylvania Avenue, NW Suite 950
Washington, DC 20006

Dear Dr. Pappas:

Please refer to your new drug application (NDA) dated and received August 17, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancomycin Hydrochloride for Injection, 500 mg/vial, 1 gram/vial, 5 gram/vial and 10 gram/vial.

We acknowledge receipt of your amendment dated July 21, 2022, which constituted a complete response to our August 25, 2021, action letter.

This NDA provides for the use of Vancomycin Hydrochloride for Injection, in adult and pediatric patients less than 18 years of age, as follows:

For intravenous administration, for the treatment of:

- Septicemia
- Infective Endocarditis
- Skin and Skin Structure Infections
- Bone Infections
- Lower Respiratory Tract Infections

For oral administration, for the treatment of:

- *Clostridioides difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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) 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

Submit final printed carton and container labeling that are identical to the enclosed carton and container, 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 *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 210274**." 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 Vancomycin Hydrochloride for Injection shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

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 the guidance for industry *Contents of a Complete Submission for the Evaluation of*

[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.

Proprietary Names. and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

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.

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 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).

[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

If you have questions, please call Sheel Shah, PharmD, Regulatory Project Manager, at 240-402-3968.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

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/

PETER W KIM
01/20/2023 08:19:48 PM