CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

213895Orig1s000

Trade Name:	VANCOMYCIN
Generic or Proper Name:	Vancomycin
Sponsor:	Xellia Pharms APS
Approval Date:	August 26, 2021
Indication:	VANCOMYCIN injection administered intravenously is indicated for the treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections, and lower respiratory tract infections. VANCOMYCIN injection administered orally is indicated for the treatment of Clostridioides difficile-associated diarrhea and Entercolitis caused by Staphyloccoccus aureus (including methicillin-resistant strains).

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213895Orig1s000

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 213895

NDA APPROVAL

Xellia Pharmaceuticals, ApS
c/o Xellia Pharmaceuticals USA, LLC
Attention: Mark Kopulos
US Agent & Senior Director, Regulatory Affairs
2150 E Lake Cook Road, Suite 1015
Buffalo Grove, IL 60089

Dear Mr. Kopulos:

Please refer to your new drug application (NDA) dated September 20, 2019, received September 20, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancomycin Injection, 5 g/100 mL.

We acknowledge receipt of your amendment dated February 26, 2021, which constituted a complete response to our March 20, 2020, action letter.

This NDA provides for the use of Vancomycin Injection 5g/100mL **administered intravenously** for the treatment of:

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

The NDA also provides for Vancomycin Injection 5g/100mL **administered orally** 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 carton and container labeling submitted on August 18, 2021, 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 213895." Approval of this submission by FDA is not required before the labeling is used. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Vancomycin Injection 5g/100mL shall be 24 months from the date of manufacture when stored at 15°C - 25°C, protected from light.

[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 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 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 any questions, call Christopher L. Smith, PharmD, MPH, Regulatory Project Manager at (301) 796-4851.

Sincerely,
{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy 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

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/

DMITRI IARIKOV
08/26/2021 02:08:05 PM