NDA 220787

NDA APPROVAL

Wockhardt BIO AG
c/o VRT Pharma Consulting LLC
Attention: Vijay Tammara, PhD
Chief Executive Officer/President
402 Jacobs Court
Exton, PA 19341

Dear Dr. Tammara:

Please refer to your new drug application (NDA) received September 30, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zaynich (cefepime and zidebactam) for injection.

This NDA provides for the use of Zaynich (cefepime and zidebactam) for injection for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible microorganisms.

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 the 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

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 labeling 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 220787**." 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 Zaynich (cefepime and zidebactam) for injection shall be 24 months from the date of manufacture when stored at 2°C to 8°C (36°F to 46°F); brief excursions are permitted up to 25°C (77°F).

ADVISORY COMMITTEE

Your application for Zaynich was not referred to an FDA advisory committee because the application did not raise significant public health questions on the role of the drug in the treatment of cUTI.

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 deferring submission of your pediatric studies because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these

[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.

postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

4999-1 Conduct an open-label, non-comparative study to evaluate the pharmacokinetics, safety, and tolerability of single and multiple doses of cefepime and zidebactam in pediatric patients from 2 months to less than 18 years of age with complicated urinary tract infections (cUTI), including pyelonephritis.

Draft protocol submission:	08/2026
Final protocol submission:	11/2026
Study completion:	12/2029
Final report submission:	04/2030

4999-2 Conduct an open-label, non-comparative study to evaluate the pharmacokinetics, safety, and tolerability of single and multiple doses of cefepime and zidebactam in pediatric patients from birth to less than 2 months of age with late onset sepsis, cUTI, or other confirmed serious acute gram-negative infections.

Draft protocol submission:	08/2026
Final protocol submission:	11/2026
Study completion:	12/2029
Final report submission:	04/2030

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 protocols to your IND 116002, 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 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.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA

[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.

to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to assess a signal of serious risk of the development of drug resistance to cefepime and zidebactam.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess this serious risk.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following study:

4999-3 Conduct a US surveillance study over a five-year period after the introduction of cefepime and zidebactam to the market to determine if bacterial resistance or decreased susceptibility to cefepime and zidebactam is occurring in the target population of bacteria that are in the approved cefepime and zidebactam label.

The timetable you submitted on May 05, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	01/2027
Final Protocol Submission:	06/2027
First Interim Report:	06/2028
Second Interim Report:	06/2029
Third Interim Report:	06/2030
Fourth Interim Report:	06/2031
Fifth Interim Report:	06/2032
Study Completion:	12/2032
Final Report Submission:	03/2033

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.[1]

Submit clinical protocol(s) to your IND 116002 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o) , REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o), REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o).**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4999-4 Method revalidation studies for the analytical procedure used for the determination (b) (4) and submission of results of the revalidation of the analytical method after incorporation of internal reference standard. Report on method equivalency comparing the results of the existing method and the revalidated method for determination of (b) (4) .

The timetable you submitted on May 15, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 09/2026

This information should be submitted as a Prior Approval Supplement. The final report submission should be identified as “Final Report Submission for PMC 4999-4 in addition to being identified as a “Prior Approval Supplement.”

4999-5 Submission of results of the leachable impurity assessment on the (b) (4) month long-term stability samples from three registration drug product batches. Any leachables present above the Safety Concern Threshold (SCT) of 5 mcg/day will be identified. Toxicological risk assessments and permitted daily exposure (PDE) values for all identified leachables occurring at levels that exceed (b) (4) mcg/mL corresponding to a daily exposure of 5 mcg/day will be provided. PDE determinations will follow the

recommended methods described in the ICH Q3C(R9) and ICH Q3D(R2) guidances and full method details for each PDE determination will be submitted to the FDA, including all PDE calculations, determinations of LOELs, NOELs, and uncertainty factors, and the sources of all supporting literature and/or study findings.

The timetable you submitted on May 15, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 07/2026

This information should be submitted as a Prior Approval Supplement. The final report submission should be identified as "Final Report Submission for PMC 4999-5 in addition to being identified as a "Prior Approval Supplement".

4999-6 Three batches of the drug product will be manufactured at the target fill weight of (b) (4)% of the labeled claim and with ±(b) (4)% individual fill weight specification limits, including evaluation of low filling speed of (b) (4) VPM in one batch and high filling speed of (b) (4)VPM in a separate batch.

The timetable you submitted on May 15, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 01/2027

For PMC 4999-6, the following information will be submitted to the Agency for the three batches:

- Drug product release testing data for all three batches.
- An Excel spreadsheet with individual fill weight results, mean, and standard deviation for each IPC check, and statistics summary for the fill weight data including all the rejected units for each batch.
- Chronological and distribution plots of the individual fill weight results.
- Process capability analysis with respect to the proposed LSL/USL of (b) (4) including both Cpk and Ppk calculation using "Sigma within" and "Sigma total", respectively.
- Tentative filled vial rejection limit based on available batch data and to be included in the intended MBR. Excursions beyond the proposed limit will be investigated to identify the root cause. The tentative rejection limit will be finalized based on manufacturing batch data from a statistically significant number of commercial batches.

This information should be submitted as a Prior Approval Supplement. The final report submission should be identified as "Final Report Submission for PMC 4999-6 in addition to being identified as a "Prior Approval Supplement".

Submit clinical protocols to your IND 116002 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," **or** "**Postmarketing Commitment Correspondence**."

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]

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

REPORTING REQUIREMENTS

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

[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

POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

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[7].

If you have any questions, email Lori Kolejian, MS, MSAMB, Regulatory Project Manager, at Lori.kolejian@fda.hhs.gov, or call (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Acting Deputy Director
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

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

[7] https://www.uspnf.com/

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
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