NDA 206494/S-014

SUPPLEMENT APPROVAL

Abbvie Inc
Attention: Janki Doshi
Sr. Manager, Regulatory Affairs
100 Park Avenue
Florham Park, IL 07932

Dear Janki Doshi:

Please refer to your Supplemental New Drug Application (sNDA) dated October 30, 2024, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AVYCAZ (ceftazidime and avibactam) for injection.

We also refer to our approval letter dated April 25, 2025, which contained the following error: Corrected the Proprietary Name and Prescribing Information.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 25, 2025, the date of the original approval letter.

This "Changes Being Effected" supplemental new drug application provides for Revisions to the container label, carton labeling and Section 11 DESCRIPTION of the United States Prescribing information (USPI) to align the labeled amount of ceftazidime (2 g) with respect to the equivalent amount of ceftazidime pentahydrate/sodium carbonate, sodium carbonate and the labeled amount of avibactam (0.5 g) with respect to the amount of avibactam sodium.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions indicated, the enclosed labeling (text for the perscribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 "Product Correspondence – Final Printed Carton and Container Labels for approved NDA 206494/S-014." Approval of this submission by FDA is not required before the labeling is used.

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, call Dahlia A. Walters, Regulatory Business Process Manager, at (301) 796 - 8427.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor
Division of Product Quality Assessment XI
Office of Product Quality Assessment II Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

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