



NDA 206494/S-005  
NDA 206494/S-006

**SUPPLEMENT APPROVAL  
FULFILLMENT OF POSTMARKETING  
REQUIREMENTS**

Allergan Sales, LLC  
Attention: Amjad Iqbal, PharmD  
Executive Director, Regulatory Affairs  
5 Giralda Farms  
Madison, NJ 07940

Dear Dr. Iqbal:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 14, 2018, received September 14, 2018, and your amendments, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Avycaz (ceftazidime and avibactam) for injection.

These Prior Approval supplemental new drug applications provide for expansion of the use of Avycaz (ceftazidime and avibactam) for injection for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) to include patients 3 months to less than 18 years of age.

These trials were conducted to fulfill the following Postmarketing Requirements listed in our February 25, 2015, action letter:

- 2862-1 Conduct a randomized multicenter, active-controlled trial to evaluate the safety and tolerability of AVYCAZ (ceftazidime-avibactam) in children from 3 months to less than 18 years of age with cUTI. The dose for this study will be determined upon review of the data to be submitted by June 2015 from a single-dose, multicenter, non-comparative study assessing the pharmacokinetics of AVYCAZ (ceftazidime-avibactam) in pediatric patients from 3 months to less than 18 years of age.
- 2862-2 Conduct a randomized, multicenter, active-controlled trial to evaluate the safety and tolerability of AVYCAZ (ceftazidime-avibactam) in children from 3 months to less than 18 years of age with cIAI. The dose for this study will be determined upon review of the data to be submitted by June 2015 from a

single-dose, multicenter, non-comparative study assessing the pharmacokinetics of AVYCAZ (ceftazidime-avibactam) in pediatric patients from 3 months to less than 18 years of age.

## **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **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 the enclosed labeling (text for the Prescribing 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 from 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

## **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 note that you have fulfilled the requirements for pediatric studies for ages 3 months to less than 18 years of age for these applications.

## **FULFILLMENT OF POSTMARKETING REQUIREMENT(S)**

We have reviewed your submissions dated September 14, 2018, containing the final reports for the aforementioned postmarketing requirements listed in the February 25, 2015, approval letter and conclude that the requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the February 25, 2015, and February 1, 2018, approval letters that are still open.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **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 Eva Zuffova, Regulatory Project Manager, at 301-796-0697.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling  
Prescribing Information

-----  
**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/  
-----

SUMATHI NAMBIAR  
03/14/2019 10:31:58 AM