NDA 200327/S-022

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Allergan Sales, LLC
Attention: Sandra P. Silva, MS, MBA
Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Silva:

Please refer to your supplemental new drug application (sNDA) dated November 13, 2018, received November 13, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Teflaro (ceftaroline fosamil) for Injection.

This Prior Approval supplemental new drug application provides for a change in the indicated patient population for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) to include pediatric patients from birth to less than 2 months of age.

The labeling change to include pediatric patients from birth to less than 2 months of age in the ABSSSI indication is based on the results of a trial conducted to fulfill the following Postmarketing Requirement listed in the October 29, 2010, approval letter:

> 1692-005: Perform a randomized comparison of Teflaro (ceftaroline fosamil) and comparator in infants < 2 months of age with ABSSSI and community-acquired bacterial pneumonia (CABP) including patients with infections suspected or demonstrated to be caused by MRSA.

Specifically, updates have been made to the **HIGHLIGHTS, INDICATIONS AND USAGE** (Section 1), **DOSAGE AND ADMINISTRATION** (Section 2), **ADVERSE REACTIONS** (Section 6), **USE IN SPECIFIC POPULATIONS** (Section 8), **CLINICAL PHARMACOLOGY** (Section 12), and the **CLINICAL STUDIES** (Section 14), of the prescribing information (PI) to reflect use in pediatric patients less than 2 months of age.

In addition, eosinophilic pneumonia was added to the **ADVERSE REACTIONS** (Section 6), **Postmarketing Experience** (Subsection 6.2) of the PI.

Additional minor changes were also made to other sections of the PI and corresponding changes were made to the carton labeling as applicable.

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.

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), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 this supplemental application, 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).

CARTON LABELING

Submit final printed carton labeling that are identical to the enclosed carton labeling no more than 30 days after they are printed. Please submit the 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 Labeling for approved NDA 200327/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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[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.

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 CABP is infrequent in this age group, we are waiving the pediatric study requirement for ages 0 to less than 2 months for this indication as necessary studies are impossible or highly impracticable.

We note that you have fulfilled the pediatric study requirements for all relevant pediatric age groups for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have reviewed your submission dated November 13, 2018, containing the final reports for the aforementioned postmarketing requirement (1692-005) listed in the October 29, 2010, approval letter and conclude that the requirement is fulfilled.

This completes all your postmarketing requirements and postmarketing commitments acknowledged in our October 29, 2010 approval letter.

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 *Providing Regulatory Submissions in Electronic and*

Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

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 FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5] For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.[6]

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

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton Labeling

[3] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[6] http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

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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
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