NDA 50-684/S-096
NDA 50-750/S-043

SUPPLEMENT APPROVAL
COMPLETION OF PREA STUDY

Wyeth Pharmaceuticals LLC
a subsidiary of Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Abarshalin:

Please refer to your supplemental new drug applications (sNDAs) dated April 26, 2019, received April 26, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50-684/S-096 Zosyn (piperacillin and tazobactam) for Injection
NDA 50-750/S-043 Zosyn (piperacillin and tazobactam) Injection in GALAXY Containers

We acknowledge receipt of your major amendment dated December 20, 2019, which extended the goal date by three months.

These Prior Approval supplemental new drug applications provide for expansion of the use of ZOSYN for the treatment of nosocomial pneumonia to include patients from 2 months to less than 18 years of age.

These supplements were submitted in follow-up to the January 25, 2008, Agency letter wherein a determination was made that trials in the pediatric population for the treatment of nosocomial pneumonia would be necessary to fulfill the requirements of the Pediatric Research Equity Act (PREA) for ZOSYN for this indication. In addition, this letter waived the pediatric study requirement for ages from birth to less than 3 months for this indication because it is impossible or highly impracticable to conduct studies in this age group.

APPROVAL & LABELING

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

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 these NDAs, 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).

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.

[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.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

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 Naseya Minor, Regulatory Project Manager, at 301-796-0756.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infectives
Office of Infectious Diseases
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
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