NDA 50-684/S-095
NDA 50-750/S-042

SUPPLEMENT APPROVAL

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 29, 2019, received April 29, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

> NDA 50-684/S095 Zosyn (piperacillin and tazobactam for Injection) and
> NDA 50-750/S-042 Zosyn (piperacillin sodium and tazobactam sodium injection) in Galaxy Containers.

These Prior Approval supplemental new drug applications provide for the addition of the adverse reaction of seizures to the **HIGHLIGHTS**, Section **5 WARNINGS AND PRECAUTIONS, Subsection 5.4 Central Nervous System, and Section 6 ADVERSE REACTIONS, Subsection 6.2 Post-Marketing Experience,** of the prescribing information. **In addition, Section 12 CLINICAL PHARMACOLOGY, Subsection 12.4 Microbiology** was updated with the labeling recommendations provided in the FDA guidance Microbiology Data for Systemic Antibacterial Drugs - Development, Analysis, and Presentation. Minor editorial edits were also made throughout the PI.

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 with minor editorial revisions listed below and reflected in the enclosed labeling:

In the Highlights, the heading "**Recent Major Changes**" was revised to add an (s) at the end as defined by regulation, and the CNS abbreviation was spelled out (i.e., Central Nervous System) since this is the first use of this terminology in the PI.

Clostridium difficile has been changed to *Clostridioides difficile* throughout the PI to be consistent with the current taxonomic classification of the bacterium.

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 sNDAs, 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).

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}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

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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.

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/

DMITRI IARIKOV
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