DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050684/S-088, S-089, S-090
NDA 050750/S-037, S-038, S-039

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Worldwide Safety & Regulatory
235 East 42nd Street
New York, NY10017-5755

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received August 19, 2016 (050684/S-088, 050750/S-037), September 15, 2016 (050684/S-089, 050750/S-038), and December 16, 2016 (050684/S-090, 050750/S-039), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50684	Zosyn (piperacillin and tazobactam for injection)
NDA 50750	Zosyn (piperacillin sodium and tazobactam sodium injection) in Galaxy Containers

The following Changes Being Effected supplemental new drug applications revise the labeling as indicated below:

NDA 050684/S-088, NDA 050750/S-037

WARNINGS AND PRECAUTIONS section, nephrotoxicity information (5.5).

NDA 050684/S-090, NDA 050750/S-039

WARNINGS AND PRECAUTIONS (5.5) and **DRUG INTERACTIONS** section (7.3), addition of piperacillin/tazobactam and vancomycin interaction.

The following Prior Approval supplemental new drug applications revise the labeling as indicated below:

NDA 050684/S-089, NDA 050750/S-038

USE IN SPECIFIC POPULATIONS section, **Pregnancy** (8.1) and **Lactation** (8.2) subsections revised according to the Pregnancy and Lactation Labeling Rule.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended, and 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 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 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 MS Word format, that includes the changes 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).

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOSEPH G TOERNER
05/05/2017