



NDA 050684/S-084, S-086  
NDA 050750/S-034, S-035

**SUPPLEMENT APPROVAL**

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

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received November 6, 2015 (050684/S-084, 050750/S-034), and February 17, 2016 (050684/S-086, 050750/S-035), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

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

These “Changes Being Effected” supplemental new drug applications revise the labeling as indicated below:

NDA 050684/S-084, NDA 050750/S-034

- WARNINGS AND PRECAUTIONS section, Electrolyte Effects subsection (5.6) to update quantity of sodium.
- DRUG INTERACTIONS section to add a new subsection on co-administration with vancomycin (7.3).

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- ADVERSE REACTIONS section, Post-Marketing Experience subsection (6.2), to add eosinophilic pneumonia and dermatitis exfoliative.
- Relocation of some adverse reactions in different system organ class (SOC) according to MedDRA v.18.1.

Also, minor editorial changes have been made.

## **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).

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If you have any questions, call Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

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: Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
06/10/2016