DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050684/S-063, S-074, S-080
NDA 050750/S-021, S-026, S-030

SUPPLEMENT APPROVAL

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

Dear Mr. Abarshalin:

Please refer to your supplemental New Drug Applications (sNDA) for the following:

NDA Number	Drug Name	Supplement Number	Submission Date	Date Received
050684	Zosyn (piperacillin and tazobactam for injection, USP)	S-063 S-074 S-080	June 30, 2009 April 6, 2012 May 2, 2013	June 30, 2009 April 6, 2012 May 2, 2013
050750	Zosyn (piperacillin and tazobactam injection) in Galaxy Containers (PL 2040 Plastic)	S-021 S-026 S-030	June 30, 2009 April 6, 2012 May 2, 2013	June 30, 2009 April 6, 2012 May 2, 2013

We acknowledge receipt of your amendments dated June 22, 2012 and September 5, 2013, to NDA 50-684/S-063 and NDA 50-750/S-021.

The "Prior Approval" supplemental applications submitted on June 30, 2009, provide for revisions to the labeling to comply with the requirements of the FDA's Physician Labeling Rule (PLR).

The "Changes Being Effected" supplemental applications submitted on April 6, 2012, provide for a new warning regarding serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis.

The "Prior Approval" supplemental applications submitted on May 2, 2013, provide for revisions to the Susceptibility Interpretive Criteria for *Pseudomonas aeruginosa*.

We have completed our review of these supplemental applications, as amended. 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 (text for the package insert), 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 these supplemental applications, 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}

Sumathi Nambiar, M.D., M.P.H.
Acting Director
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/

SUMATHI NAMBIAR
09/06/2013