DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050684/S-055, S-061
NDA 050750/S-016, S-020

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals, Inc.
Attention: Priso Epale
Associate Director, Worldwide Regulatory Strategy
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Epale:

Please refer to your supplemental New Drug Applications (sNDA's), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Drug Name	Supplement Number	Submission Date	Date Received
050684	Zosyn (piperacillin and tazobactam) for Injection, 2.25g, 3.375g and 4.5g Vials and 40.5 Bulk Pharmacy Vials	S-055 S-061	November 19, 2007 January 30, 2009	November 19, 2007 January 30, 2009
050750	Zosyn (piperacillin sodium/tazobactam sodium) in Galaxy Containers	S-016 S-020	November 20, 2007 January 30, 2009	November 20, 2007 January 30, 2009

We acknowledge receipt of your amendments, dated August 18, 2010 for NDA 050684/S-061 and NDA 050750/S-020.

The August 18, 2010 submission constituted a complete response to our August 31, 2009, action letter.

NDA 050684/S-055, NDA 050750/S-016:
These "Prior Approval" labeling supplements provide for revisions to update the information under the Directions for Reconstitution and Dilution for Use section of the label.

NDA 050684/S-061, NDA 050750/S-020:
These "Prior Approval" labeling supplements provide for labeling in the **DOSAGE AND ADMINISTRATION** section to facilitate Y-site co-administration of Zosyn with gentamicin in the presence of 5% dextrose or 0.9% sodium chloride.

We have completed our review of these supplemental applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling.

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 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 numbers and annual report dates.

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, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}
Katherine Laessig, M.D.
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:
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/

KATHERINE A LAESSIG
05/11/2012