NDA 050750/S-048

APPROVAL LETTER

Wyeth Pharmaceuticals LLC
Attention: Mikhail Abarshalin
Director, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-7555

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Application (sNDA) dated September 30, 2021, received September 30, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZOSYN (piperacillin and tazobactam) injection 2 g/0.25 g in 50 mL, 3 g/0.375 g in 50 mL, & 4 g/0.5 g in 100 mL.

We also refer to our approval letter dated March 23, 2022, which contained the following error: Incorrect Carton and Container Labeling Enclosed

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 23, 2022, the date of the original approval letter.

This "Changes Being Effected" supplemental new drug application provides for:

> Updated container (IV BAG) labels and carton labeling for ZOSYN (piperacillin and tazobactam) injection in Galaxy Container to include the statement "Handle frozen product containers with care. Product containers may be fragile in the frozen state.", based on the FDA recommendation.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA**

050750/S-048." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, contact Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

David B. Lewis, Ph.D.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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