DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-684/S-039
NDA 50-750/S-009

Wyeth Pharmaceuticals
Attention: Mary Ellen Menz, RN, MBA, JD
Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, Pennsylvania 19101-8299

Dear Ms. Menz:

Please refer to your supplemental new drug applications dated November 4, 2003, received November 6, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zosyn® (sterile piperacillin sodium and tazobactam sodium) (NDA 50-684), and Zosyn® (piperacillin and tazobactam sodium) in Galaxy® Containers (PL 2040 plastic) (NDA 50-750). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated May 12, July 27 (50-684), July 28 (50-750), October 22 (S-039), and October 25 (S-009), 2004. Your submissions of July 27 and July 28, 2004 constituted a complete response to our May 5, 2004 action letter.

These supplemental new drug applications provide for additional information in the **Drug/Laboratory Test Interactions** subsection of the **PRECAUTIONS** section and revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We have completed our review of these applications and they are approved, effective on the date of this letter. The final printed labeling submitted on October 22 (S-039), and October 25 (S-009), 2004 is acceptable.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

/s/

Janice Soreth

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