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**Wyeth**

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May 10, 2006

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket 2006P-0173; Clarifying Supplement to Citizen Petition

Dear Sir or Madam:

Wyeth hereby submits additional information to supplement its Citizen Petition submitted on April 25, 2006 (Docket No. 2006P-0173). In that petition, Wyeth discusses the compatibility of Zosyn® with Lactated Ringer's Solution and the aminoglycoside antibiotics amikacin and gentamicin. Wyeth wishes to now clarify the compatibility profile of Zosyn® with respect to gentamicin.

Zosyn® is a combination antibacterial product used for treating certain infections. Wyeth distributes the product in several presentations: (1) standard vials, (2) ADD-Vantage® vials, (3) pharmacy bulk vials, and (4) Galaxy® containers. Zosyn® Galaxy® containers are available as 2.25g per 50mL, 3.375g per 50mL and 4.5g per 100mL. When distributed in vials, Zosyn® is in the form of a lyophilized powder; when in Galaxy® containers, it is in the form of a frozen solution.

Zosyn® is compatible with Lactated Ringer's Solution and may be co-administered via Y-site infusion with the aminoglycoside antibiotics amikacin and gentamicin. When Zosyn® is supplied in 3.375g per 50mL Galaxy® containers, however, the drug cannot be co-administered with gentamicin due to the higher concentration of piperacillin and tazobactam present in those containers. The higher concentration of piperacillin and tazobactam in this Galaxy® container does not affect the product's compatibility with Lactated Ringer's Solution or amikacin.

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When Zosyn® is presented in vials or other types of containers, whether in standard vials, ADD-Vantage® vials, pharmacy bulk vials, or other sizes of Galaxy® containers, it is fully compatible with Lactated Ringer's Solution, amikacin and gentamicin.

Respectfully submitted,

A handwritten signature in cursive script that reads "Geoffrey M. Levitt/cph".

Geoffrey M. Levitt  
Vice President & Chief Counsel  
Regulatory and Research