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**UPS OVERNIGHT EXPRESS**

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5600 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

**CITIZEN PETITION**

Sandoz Inc. submits this petition under section 505 (j)(2)(c) of the Federal Food, Drug and Cosmetic Act, 21 CFR § 314.93 and in accordance with the procedural requirements set forth in 21 CFR § 10.30 to request the Commissioner of Food and Drugs to make a determination that the discontinued formulation of the Reference Listed Drug, Zosyn® (piperacillin and tazobactam for injection), the subject of NDA 50-684, held by Wyeth Pharmaceuticals Inc., is suitable for submission in an Abbreviated New Drug Application (ANDA).

**A. Action Requested**

Sandoz Inc. requests that the Commission of Food and Drugs (FDA) make a determination that the discontinued formulation of Wyeth Pharmaceuticals' Zosyn® (piperacillin and tazobactam for injection) packaged in convention and ADD-Vantage vials, containing 2.25 g, 3.375 g and 4.5 g of piperacillin sodium and tazobactam sodium, equivalent to 2 grams of piperacillin and 0.25 g of tazobactam, 3 grams of piperacillin and 0.375 g of tazobactam, 4 grams of piperacillin and 0.5 g of tazobactam per vial, was not discontinued for safety and efficacy reasons.

Sandoz Inc. particularly requests the FDA make a determination that the proposed generic product referring to the originally approved formulation (now discontinued) would not render the product less safe or effective than the currently marketed innovator's product. Sandoz further requests the FDA accept its Abbreviated New Drug Applications (ANDAs) for Piperacillin and Tazobactam for injection, 2.25 g, 3.375 g and 4.5 g, packaged in convention and ADD-Vantage vials (hereinafter referred to as "proposed generic products") containing 2.25 g, 3.375 g and 4.5 g of piperacillin sodium and tazobactam sodium,

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equivalent to 2 grams of piperacillin and 0.25 g of tazobactam, 3 grams of piperacillin and .375 g of tazobactam, 4 grams of piperacillin and 0.5 g of tazobactam per vial, without edetate disodium and citric acid.

## **B. Statement of Grounds**

The Reference Listed Drug, Zosyn® (piperacillin and tazobactam for injection), the subject of NDA 50-684, held by Wyeth Pharmaceuticals Inc. was first approved October 22, 1993. The product was supplied in a conventional vial and ADD-Vantage vial containing 2.25 g, 3.375 g and 4.5 g of piperacillin sodium and tazobactam sodium, equivalent to 2 grams of piperacillin and 0.25 g of tazobactam, 3 grams of piperacillin and 0.375 g of tazobactam, 4 grams of piperacillin and 0.5 g of tazobactam per vial. A copy of the previously approved package insert (Appendix A) for this reference listed product, Zosyn® for injection, is provided.

On September 30, 2005, FDA approved a reformulation of the drug product and labeling changes for Zosyn® (piperacillin and tazobactam for injection), under the subject NDA 50-684, Supplement Number 045. In this supplement, Wyeth Pharmaceuticals Inc. added edetate disodium and citric acid. A copy of the cover letter supporting this newly approved reformulation and package insert (Appendix B) for the reference listed product, Zosyn® for injection, is provided. The physician insert to support this supplement is currently not available, therefore it could not be provided in this petition.

It is known from the Code of Federal Regulations that when an ANDA makes reference to a discontinued label of a drug, FDA may still approve the ANDA upon determination that the formulation was not withdrawn for reasons of safety or effectiveness (21 U.S.C. Section 355 (j)(6) and 21 CFR §§ 314.122 and 314.161). Similarly, FDA is also authorized to approve an ANDA that omits in its labeling an aspect of the listed drug. In this circumstance, omission from the NDA's labeling of inactive ingredients is allowed if the omission does not render the generic drug product less safe or effective than the listed drug. (21 CFR § 314.127 (a)(7)).

Sandoz is not aware of any documentation which establishes that the original formulation of the Zosyn® for injection was discontinued for safety or efficacy reasons.

Sandoz proposed generic product is identical to the discontinued formulation of Zosyn® for injection. Sandoz proposed generic product will also be supplied in a conventional vial and ADD-Vantage vial containing 2.25 g, 3.375 g and 4.5 g of piperacillin sodium and tazobactam sodium, equivalent to 2 grams of piperacillin and 0.25 g of tazobactam, 3 grams of piperacillin and 0.375 g of tazobactam, 4 grams of piperacillin and 0.5 g of tazobactam per vial. A copy of Sandoz proposed physician insert is provided (Attachment C).



Sandoz proposed generic product, which is subject of this petition, is identical to the originally approved Zosyn® (piperacillin and tazobactam for injection), under the subject NDA 50-684.

Accordingly, Sandoz Inc. believes that the information presented in this Citizen's Petition supports the fact that the product was not withdrawn for the reasons of safety and efficacy and requests that its Piperacillin and Tazobactam for Injection products be eligible for approval upon completion of the review process.

### **C. Environmental Impact**

An Environmental Impact Analysis Report for the action requested is not required as cited under 21 CFR 25.31 (a).

### **D. Economic Impact**

Information regarding economic impact will be made upon request.

### **E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petitioner.

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