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OVERNIGHT MAIL

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

**CITIZEN PETITION
(ANDA SUITABILITY PETITION)**

Sandoz Inc., hereby submits this petition under Section 505 (j) (2) (c) of the Federal Food, Drug and Cosmetic Act and pursuant to 21 CFR 314.93 to request that the Commissioner of Food and Drug Administration permit the filing of an Abbreviated New Drug Application for a drug that has the same active ingredient and dosage form listed in FDA's publication entitled, Approved Drug Products with Therapeutic Equivalence Evaluations, current Internet edition, but differs in its dosage strength (total quantity of active ingredient in the package).

A. Action Requested

By this petition, we hereby request the Agency to permit the filing of an abbreviated New Drug Application for a Piperacillin and Tazobactam for Injection, 13.5 g pharmacy bulk vial containing piperacillin sodium equivalent to 12 grams of piperacillin and tazobactam sodium, equivalent to 1.5 grams of tazobactam [containing 2.35 mEq (54 mg) of sodium]. This drug differs from the reference listed drug filed under NDA 50-750 for Wyeth Pharmaceutical Inc.'s ZOSYN® (Piperacillin and Tazobactam for Injection), a 40.5 g pharmacy bulk vial containing piperacillin sodium equivalent to 36 grams of piperacillin and tazobactam sodium, equivalent to 4.5 grams of tazobactam [containing 84.5 mEq (1,944 mg) of sodium]. Although the total dosage strength differs, the dosage amount recommended for administration to the patient remains the same.

2006P-0095

CPI



B. Statement of Grounds

In accordance with 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act, a petition may be filed, with the Agency, seeking permission to file an Abbreviated New Drug Application for a new drug, which differs from a "listed" drug in dosage strength. The Act stipulates that such a petition must be approved by the Agency, unless there is a finding that investigations are needed to demonstrate the safety and effectiveness of the proposed drug product.

The reference listed drug product, Wyeth Pharmaceutical Inc.'s ZOSYN® (Piperacillin and Tazobactam for Injection), 40.5 g pharmacy bulk vial, is identified in the Prescription Product list of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) as supplied in the CDER Internet home page. A printout of this listing by active ingredient details is provided in Attachment 1.

We propose to develop a pharmacy bulk package of Piperacillin and Tazobactam for Injection in a 13.5 g pharmacy bulk vial. The same formulation and route of administration as the reference listed drug Pharmacy Bulk Vial are proposed, i.e, Piperacillin and Tazobactam for Injection, for intravenous injection after constitution with a specified diluent (i.e. 0.9% Sodium Chloride for Injection, Sterile Water for Injection, Dextrose 5%, Bacteriostatic Saline/Parabens, Bacteriostatic Water/Parabens, Bacteriostatic Saline/Benzyl Alcohol, or Bacteriostatic Water/Benzyl Alcohol). The proposed product will be administered at the same dosage recommendations as the listed drug and is expected to have the same therapeutic effect when administered for use as indicated in the product labeling.

Labeling for the reference listed drug, Wyeth Pharmaceutical Inc.'s ZOSYN® (Piperacillin and Tazobactam for Injection), is included in Attachment 2. Labeling for the proposed product is substantially the same as the sections pertaining to the pharmacy bulk package dosage form of the listed drug labeling, with the exception that reference to Wyeth Pharmaceutical Inc.'s ZOSYN® (Piperacillin and Tazobactam for Injection), 40.5 g Pharmacy Bulk Vial will be replaced with "Piperacillin and Tazobactam for Injection, 13.5 g pharmacy bulk vial," and references to other dosage forms will be eliminated. The active ingredients, dosage form, route of administration and recommended dosages remain the same. The indications for use will also remain the same. A copy of the proposed draft package insert is provided in Attachment 3.

This pharmacy bulk vial is not for direct infusion. Reconstituted stock must be transferred and further diluted for I.V. infusion. The proposed strength is designed to be used in a hospital pharmacy admixture service only under a laminar flow hood. After reconstitution, entry into the vial must be made with a sterile transfer set or other sterile dispensing device, and contents should be dispensed as aliquots into intravenous solution using aseptic technique. As a result, administering Piperacillin and Tazobactam for Injection from a smaller vial size will not have any effect on the delivery of the product.



Introduction of a 13.5 g pharmacy bulk vial, will also not have an impact on the established safety and efficacy of Piperacillin and Tazobactam for Injection, and since the product is an injectable preparation to be administered at the same strength as the listed drug, a bioequivalence study is not viewed as a requirement.

C. Environmental Impact

An environmental impact analysis report is not required for this petition per 21 CFR 25.24.

D. Economic Impact

This information will be provided upon request from the Agency.

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 are unfavorable to the petition.

If you have any questions or need additional information, please feel free to contact me.

A handwritten signature in cursive script that reads 'Beth Brannan'.

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Enclosures: Attachments 1, 2 and 3