



Jean Domenico  
Manager  
Regulatory Affairs

Sandoz Inc.  
2555 W. Midway Blvd.  
P.O. Box 446  
Broomfield, CO 80038-0446  
Tel +1 303 438-4242  
Fax +1 303 438-4600  
Email: jean.domenico@sandoz.com

2011 APR 26 A 11:19

**OVERNIGHT MAIL**

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

April 21, 2011

**AMENDMENT TO CITIZEN PETITION  
(ANDA SUITABILITY PETITION)**

**SP 2006-P-0210 (Legacy No. 2006P-0095)**

To Whom It May Concern:

Sandoz Inc., is hereby submitting an amendment to our Citizen Petition (ANDA Suitability Petition) filed on March 1, 2006 in accord with Section 505 (j)(2)(c) of the Federal Food, Drug, and Cosmetic Act; 21 CFR Part 314.93.

The petition requested permission to file and Abbreviated New Drug Application for Piperacillin and Tazobactam for Injection, 13.5 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). The reference listed drug ZOSYN® (Wyeth Pharmaceutical Inc.) filed under NDA 050750 a 40.5 g lists a 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 (1944 mg) of sodium).

The petition incorrectly identified the NDA for the RLD as 050750 (as noted above). The correct RLD NDA reference should be 050684. All of the product information contained in the petition relating to the RLD is correct, it is only the actual NDA number provided which is incorrect. Please amend the petition to note that the correct RLD is:

ZOSYN® (Wyeth Pharmaceutical Inc.) filed under NDA 050684 a 40.5 g lists a 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 (1944 mg) of sodium).

The orange book information is provided on the following page for your reference.

FDA-2006-P-0210

AMD

## Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Proprietary Name Search Results from "OB\_Rx" table for query on "zosyn."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
<u>N050684</u>	AP	Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 2GM BASE/VIAL; EQ 250MG BASE/VIAL	ZOSYN	WYETH PHARMS INC
<u>N050684</u>	AP	Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL	ZOSYN	WYETH PHARMS INC
<u>N050684</u>	AP	Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 3GM BASE/VIAL; EQ 375MG BASE/VIAL	ZOSYN	WYETH PHARMS INC
<u>N050684</u>	AP	Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 4GM BASE/VIAL; EQ 500MG BASE/VIAL	ZOSYN	WYETH PHARMS INC
<u>N050750</u>		Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 40MG BASE/ML; EQ 5MG BASE/ML	ZOSYN IN PLASTIC CONTAINER	WYETH PHARMS INC
<u>N050750</u>		Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 4GM BASE/100ML; EQ 500MG BASE/100ML	ZOSYN IN PLASTIC CONTAINER	WYETH PHARMS INC
<u>N050750</u>		Yes	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	INJECTABLE; INJECTION	EQ 60MG BASE/ML; EQ 7.5MG BASE/ML	ZOSYN IN PLASTIC CONTAINER	WYETH PHARMS INC

Correct RLD Reference

This information is submitted for your review and approval.

Sincerely,

**Sandoz Inc.**

**Domenico**

**Jean**

Jean Domenico, Manager  
Regulatory Affairs

Digitally signed by Domenico Jean  
DN: cn=Domenico Jean, ou=people,  
GX, serialNumber=405645, dc=com,  
novartis  
Date: 2011.04.25 09:50:20 -06'00'

Enclosures

JD/kl

**UPS Internet Shipping: View/Print Label**

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

**3. GETTING YOUR SHIPMENT TO UPS****Customers without a Daily Pickup**

Schedule a same day or future day Pickup to have a UPS driver pickup all of your Internet Shipping packages.

Hand the package to any UPS driver in your area.

Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services<sup>SM</sup> (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the 'Find Locations' Quick link at [ups.com](http://ups.com).

**Customers with a Daily Pickup**

Your driver will pickup your shipment(s) as usual.

FOLD HERE

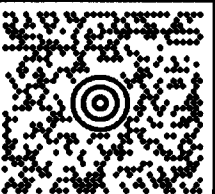
INEZ CAMPBELL  
303-438-4507  
SANDOZ INC.  
2555 WEST MIDWAY BOULEVARD  
BROOMFIELD CO 80020

0.0 LBS LTR 1 OF 1

**SHIP TO:**

DIVISION OF DOCKET'S MANAGEMENT  
FOOD AND DRUG ADMINISTRATION  
ROOM 1061 (HFA-305)  
5630 FISHERS LANE

**ROCKVILLE MD 20857-0001**



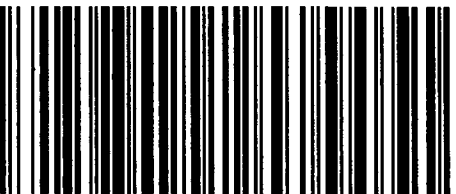
**MD 207 9-83**



**UPS NEXT DAY AIR**

TRACKING #: 1Z 802 754 01 9374 8496

**1**



BILLING: P/P

Reference#1: Citizen Pet piptazo

UIS 13.1.13. WXPTE60 12.0A 01/2011

