



**URGENT DRUG RECALL**  
Reissuance of letter dated October 10, 2011  
To correct expiration dates for two lots\*  
Refer to Reply Form, page 4.

<i>Product</i>	<i>NDC Number</i>	<i>Lot</i>
<b>Piperacillin and Tazobactam for Injection, 2.25 grams / ADD-Vantage® Vial</b>	<b>0409-3374-02</b>	<b>010018M; 010198M; 040108M; 950028M; 950038M</b>
<b>Piperacillin and Tazobactam for Injection, 3.375 grams / ADD-Vantage® Vial</b>	<b>0409-3378-13</b>	<b>010048M; 010068M; 010078M; 020308M; 030108M; 030118M; 040138M; 950088M</b>
<b>Piperacillin and Tazobactam for Injection, 4.5 grams / ADD-Vantage® Vial</b>	<b>0409-3379-04</b>	<b>010098M; 950098M; 950108M</b>

October 20, 2011

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling sixteen lots of Piperacillin and Tazobactam for Injection identified above due to out-of-specification results at the 12-month stability testing interval for subvisible particulate counts. Further testing of retained samples of on market lots resulted in additional lots being out-of-specification for particulate counts.

These lots were distributed December 2010 through August 2011. Hospira has not received any reports of adverse events associated with this issue. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

These lots were manufactured by Sandoz GmbH for Hospira. Sandoz has initiated an investigation to determine the root cause and corrective and preventive actions.

**Please check your inventory and immediately quarantine any affected product.** Complete the attached Reply Form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. Inform healthcare professionals in your organization of this recall.

Return affected product to Stericycle using the label provided with this letter. Call Stericycle at 1-866-300-2207 if you have not received a return label or require additional labels for returning the affected product. To ensure proper and timely credit, follow the instructions on the reply form for returning the product. Include your Hospira customer number (if applicable) and information about your wholesaler/distributor from whom you purchased the affected product (if applicable), and include a copy of your PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).

This recall is being conducted to the medical facility level. Therefore, **if you have distributed the product further, notify your accounts that received the product identified above of this recall** and ask them to fax the reply form to the number on the form and follow the instructions provided on the form for returning product.

Replacement product is available in alternate packaging configurations. Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representative to order replacement product in flip top vials.

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Hospira, Inc.  
275 North Field Drive  
Lake Forest, IL 60045  
(224) 212-2000  
[www.hospira.com](http://www.hospira.com)

FA109-04 (A)



For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 (Available 24 hours a day/7 days per week)	Medical inquiries

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Grace Breen  
Vice President, Commercial Quality

2505\_02\_02AS

Hospira, Inc.  
275 North Field Drive  
Lake Forest, IL 60045  
(224) 212-2000  
[www.hospira.com](http://www.hospira.com)

FA109-04 (A)

**Urgent Drug Recall Reply Form – Response Required**  
**Piperacillin and Tazobactam for Injection, USP**  
**NDC 0409-3374-02; NDC 0409-3378-13; NDC 0409-3379-04**



**Check your inventory and complete the information below, even if you do not have the affected product.**  
*Failure to complete all sections of this page may result in improper, delayed or denied credit.*

**Fax the completed form to 1-866-462-9888 or e-mail the completed form to hospira2505@stericycle.com.**  
**To obtain a return label or if you have questions about this form call Stericycle at 1-866-300-2207.**

<b>Required Information</b>	
Business Name	Phone Number
Address/City/State/Zip	DEA #
Hospira Customer Number (ship to #) if applicable	Your reference # (e.g. PO, Debit Memo or Invoice #)
Completed by: Printed Name/Signature/Date	

I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

I have affected product (fill out and return all pages of the form to Stericycle via the fax/e-mail above and return the product per the instructions below).

Lot Number	Wholesaler/Distributor Name <small>If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, name, and invoice number. If you purchased directly from Hospira leave this section blank.</small>	QTY	PO, Debit memo or Invoice
	1.		
	2.		
	1.		
	2.		
	1.		
	2.		

If affected product is not being returned, please explain:

- ✓ Have you distributed the product further to the retail level? YES\_\_\_ NO\_\_\_
- ✓ If yes, have you notified your retail customers? YES\_\_\_ NO\_\_\_ (if no, explain below)

**Urgent Drug Recall Reply Form – Response Required**  
**Piperacillin and Tazobactam for Injection, USP**  
**NDC 0409-3374-02; NDC 0409-3378-13; NDC 0409-3379-04**



Business Name \_\_\_\_\_ Hospira Customer No. \_\_\_\_\_

Lot	Expiration Date	Qty of vials to be returned
<b>NDC 0409-3374-02 Piperacillin and Tazobactam for Injection, 2.25 grams / ADD-Vantage® Vial</b>		
010018M	<b>01/01/2013*</b>	
010198M	<b>01/01/2013*</b>	
040108M	04/01/2013	
950028M	11/01/2012	
950038M	11/01/2012	
<b>NDC 0409-3378-13 Piperacillin and Tazobactam for Injection, 3.375 grams / ADD-Vantage® Vial</b>		
010048M	01/01/2013	
010068M	01/01/2013	
010078M	01/01/2013	
020308M	02/01/2013	
030108M	03/01/2013	
030118M	03/01/2013	
040138M	04/01/2013	
950088M	11/01/2012	
<b>NDC 0409-3379-04 Piperacillin and Tazobactam for Injection, 4.5 grams / ADD-Vantage® Vial</b>		
010098M	01/01/2013	
950098M	11/01/2012	
950108M	11/01/2012	

**\*Corrected Expiration Dates**

**IMPORTANT RETURN INSTRUCTIONS:**

<b>Direct Customer</b> (purchased directly from Hospira) <i>Credit will be issued by Hospira</i>	<b>Indirect Customer</b> (purchased from a wholesaler/distributor) <i>Credit will be issued through the wholesaler/distributor</i>
<ul style="list-style-type: none"> <li>▪ Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).</li> <li>▪ Ship only the <i>affected product</i> to Stericycle using the prepaid return label.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Supply information for each wholesaler/distributor.</li> <li>▪ Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).</li> <li>▪ Ship only the <i>affected product</i> to Stericycle using the prepaid return label.</li> </ul>