



# URGENT DRUG RECALL

March 18, 2013.

Apotex is notifying all direct account **Wholesalers, Distributors, and Retailers** that have received impacted lots of a voluntary CLASS II recall being conducted up to the **Retail level** for the product listed below. This voluntary CLASS II recall is being conducted in coordination with the US Food and Drug Administration.

Product	Strength	NDC Number	UPC Code	Lot Number	Exp.Date	First Date of Sale	Last Date of Sale
Piperacillin and Tazobactam for Injection, USP	Please refer to attached "Impacted Lot List"						

## REASON FOR MARKET ACTION

Product lots identified in this recall notification may show precipitation / crystallization in IV bag or IV line upon reconstitution.

## HEALTH ASSESSMENT

The presence of precipitated Piperacillin / Tazobactam in reconstituted IV bag or IV line present a low likelihood of harm, with the most, likely consequence being undertreatment, potentially local venous irritation and obstruction of small capillaries..

## ACTIONS TO BE TAKEN

1. **Stop distributing and quarantine** identified lots of Piperacillin and Tazobactam for Injection, USP 40.5 gram in this notification.
2. **Wholesalers/ Distributors are to conduct a sub-recall** to retail customer or pharmacy to which you have shipped the affected lots, by informing them of the recall, requesting that they remove the affected lots from sale and return the stock to the wholesaler from which it was purchased. Your customers **should not** return stock directly back to Apotex or GENCO.
3. For customers who purchased the affected product DIRECTLY from Apotex, you are requested to conduct a physical count of affected inventory on hand. Note: Wholesaler/Distributors must also include in their count, inventory that was returned by their retail customers or pharmacy.
  - Record total inventory on hand on the Business Reply Card (BRC) included in this letter and mail to GENCO to the address listed on the BRC. **Note:** If you have NO inventory on hand, you are still required to complete the BRC and mail it back to GENCO documenting that no affected inventory is on hand.
4. **If this letter has been forwarded to a retail pharmacy or institution that has purchased affected inventory through a wholesaler/distributor:**

The below mentioned return process **DOES NOT** apply to you. Retail customers, who purchased through a wholesaler/distributor, must return the affected inventory back to the establishment from where the inventory was purchased. For these retailers/institutions please contact your Wholesaler for specific return and credit instructions. **DO NOT** return your affected inventory back to Apotex or GENCO.

5. **Returning affected inventory to GENCO. For customers who purchased affected product DIRECTLY from Apotex,** place all affected product in a shipping carton, enclose a hard copy of the completed BRC, identify the product as "Recall Product" on the outside of the shipper and apply the prepaid shipping label provided. Contact GENCO for additional return labels if required.

### Return address:

**GENCO Pharmaceutical Services**  
6101 North 64<sup>th</sup> Street  
Milwaukee, WI 53218  
Fax#: 414-459-8791  
Phone: 1-877-674-2078 (7:00am – 5:00-pm, CST Monday thru Friday)

## ADDITIONAL INFORMATION

Reimbursement or credit will be provided only for affected product returned in its original packaging. Forward your Debit Memo detailing your complete return and freight expenditures so that proper credit can be issued, as well as any subsequent Debit Memos issued for additional recall fees, to the following address:

**Apotex Corp.**  
2400 N. Commerce Parkway Suite 400  
Weston, FL 33326  
Fax#: 1-866-301-9541  
Phone: 1-800-706-5575 (8:30 a.m. to 5:00 p.m. EST Monday thru Friday)

For reimbursement purpose the recalled batch and associated paperwork must be submitted by **June 30, 2013.**

Sincerely,  
Apotex

**Piperacillin and Tazobactam for Injection, USP. – Recall March 2013.**

**Impacted Lot List**

<b>Product Labeled As</b>	<b>Strength</b>	<b>NDC Number</b>	<b>UPC Code</b>	<b>Apotex Batch Number</b>	<b>Lot Number on The Label</b>	<b>Expiry</b>	<b>First Date of Sale (mm/dd/yyyy)</b>	<b>Last Date of Sale (mm/dd/yyyy)</b>
Piperacillin and Tazobactam for Injection, USP.	40.5 gram	60505-0773-00	360505077304	KC1967	<b>503C008</b>	01/2014	09/21/2012	10/11/2012
				JY3391	<b>503B019</b>	07/2013	10/21/2011	11/07/2011
				JY3393	<b>503B020</b>	07/2013	11/03/2011	11/21/2011
				JY3394	<b>503B021</b>	07/2013	11/21/2011	12/05/2011
				JY9942	<b>503B025</b>	09/2013	01/03/2012	02/06/2012
				JZ6417	<b>503B026</b>	09/2013	02/02/2012	02/27/2012
				JZ6420	<b>503B027</b>	09/2013	02/27/2012	03/28/2012