

Dated: May 8, 2014

## URGENT DRUG RECALL

Dear Customer:

This official communication is to notify you that Zydus Pharmaceuticals USA Inc., is voluntarily recalling the mentioned below drug product:

| Product Name                   | Lot No. | Expiry | Pack Size | NDC No.      | Distribution Start Date | Distribution End Date |
|--------------------------------|---------|--------|-----------|--------------|-------------------------|-----------------------|
| Promethazine HCl Tablets, 25mg | MN9081  | 09/15  | 100's     | 68382-041-01 | 02/21/2014              | 02/27/2014            |

Zydus Pharmaceuticals USA inc. has decided to initiate voluntary recall of the above drug product based on a product complaint that was received from a pharmacist who said that she found one tablet of Atenolol 25mg in 100 count bottle of Promethazine 25mg Tablets.

Zydus Pharmaceuticals USA Inc advises its customers that have this product in stock to discontinue use/dispense/distribute and return it to Inmar Pharmaceuticals Services as per the details furnished below.

The possibility of adverse event occurrence is remote as the entire lot was packed in 100 count HDPE bottles, which is dispensed by the pharmacy and dispensing pharmacy can easily detect the presence of different pill, if at all present; therefore, we wish to conduct this recall at retail level.

Your assistance is appreciated and necessary to prevent further product usage.

Through this communication, at our cost, you are requested to organize to return the above referenced drug product in your possession. To facilitate this recall, please do the following actions:

1. Examine your available stock for the presence of above referenced lot of the drug product under the purview of this recall.
2. If you have the concerned lot number drug product in your stock, please discontinue further distribution, quarantine the affected products and return all units to: Inmar Pharmaceutical Service, South Dock, 4332 Empire Rd, Fort Worth, TX 76155. A credit memo will be issued covering the quantity of your return to Inmar.
3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at 1-817-868-5362 or email it to [recallnotice@inmar.com](mailto:recallnotice@inmar.com). If you do not possess any inventory of the lot being recall, then also we appreciate if you fill and return the "PRODUCT RECALL RESPONSE FORM"

4. If you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please complete and return the enclosed response form as soon as possible.

If you have any questions about product safety issue, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779 Option# 2.

If you have any questions about the Logistic and other issue, then please call Recall Services at 1-800-967-5952.

This recall is being made with the knowledge of the Food and Drug Administration.

We apologize for any inconvenience this voluntary recall may have caused you.

Yours Sincerely,



Prashant Desai  
Vice President – Operations

## PRODUCT RECALL RESPONSE FORM

### URGENT DRUG RECALL

Please complete the required information and fax to **1-817-868-5362**  
or email to **recallnotice@inmar.com**

**To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.**

|                     |  |
|---------------------|--|
| <b>PRODUCT NAME</b> | <b>Promethazine HCl Tablets,<br/>25mg, 100's</b> |
| <b>Lot #</b>        | <b>MN9081</b>                                    |
| <b>NDC No.</b>      | <b>68382-041-01</b>                              |
| <b>Expiry</b>       | <b>09/15</b>                                     |

No. of Bottles Purchased : \_\_\_\_\_

No. of bottles Consumed : \_\_\_\_\_

No. of bottles in Possession : \_\_\_\_\_

No. of bottles to be returned : \_\_\_\_\_

No. of Returns kit required : \_\_\_\_\_

Please mark as applicable

We currently do not have any inventory of the above listed Lot/bottles

We are notifying our customers

I have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_;

We attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product?  Yes  No

If yes, Please explain:

---

---

Please check appropriate box to describe your business

Wholesaler/Distributor

Retailers

Grocery Corporate Headquarters

Food Service/ Restaurant

Repackager

Manufacturer

Pharmacy- Retail

Hospital/ Medical Facility

Hospital Pharmacies

Medical Laboratory

Other: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Tel Number: \_\_\_\_\_

Firm Name: \_\_\_\_\_

DEA# \_\_\_\_\_

Address: \_\_\_\_\_

City/ State: \_\_\_\_\_

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc, then please provide details of your wholesaler: \_\_\_\_\_ (Name, City)

Signature: \_\_\_\_\_

Date: \_\_\_\_\_