ZyPharma

ZYDUS PHARMACEUTICALS
A GLOBAL GENERIC PHARMACEUTICAL COMPANY

ZyGenerics

Dated: December 22, 2014

URGENT DRUG RECALL

Dear Customer:

This communication is to notify you that Zydus Pharmaceuticals USA Inc. is voluntarily recalling following twelve lots of mentioned drug product at **Retail Level**:

Product Name	Lot No.	Expiry	Pack Size	NDC No.	Distribution Start Date	Distribution End Date
Benzonatate Capsules, 100mg	MP2625	02/16	100's	68382-247-01	07/21/2014	08/08/2014
Benzonatate Capsules, 100mg	MP2626	02/16	100's	68382-247-01	08/08/2014	08/25/2014
Benzonatate Capsules, 100mg	MP2627	02/16	100's	68382-247-01	08/25/2014	09/09/2014
Benzonatate Capsules, 100mg	MP4875	04/16	100's	68382-247-01	09/19/2014	10/07/2014
Benzonatate Capsules, 100mg	MP4876	04/16	100's	68382-247-01	10/06/2014	10/13/2014
Benzonatate Capsules, 100mg	MP4877	04/16	100's	68382-247-01	10/13/2014	10/20/2014
Benzonatate Capsules, 100mg	MP6482	06/16	100's	68382-247-01	10/21/2014	11/03/2014
Benzonatate Capsules, 100mg	MP6483	06/16	100's	68382-247-01	11/03/2014	11/04/2014
Benzonatate Capsules, 100mg	MP6484	06/16	100's	68382-247-01	11/03/2014	11/10/2014
Benzonatate Capsules, 100mg	MP4878	04/16	100's	68382-247-01	10/20/2014	10/22/2014
			500's	68382-247-05	08/18/2014	11/05/2014
Benzonatate Capsules, 100mg	MP6493	06/16	500's	68382-247-05	09/23/2014	10/16/2014
Benzonatate Capsules, 100mg	MP6494	06/16	500's	68382-24705	11/04/2014	11/04/2014

Zydus Pharmaceuticals USA inc. has decided to initiate voluntary recall of above mentioned lots of the Benzonatate Capsules USP, 100mg, 100's and 500's based on two product complaints involving the 200mg strength of Benzonatate Capsules. The complainant reported that he opened a sealed bottle of Benzonatate Capsules, 200mg, and found all capsules to be wet. Based on our impact assessment, we are extending this recall to additional twelve lots of Benzonatate Capsule 100mg referenced above, although we haven't received any product complaint of similar nature for 100mg Benzonatate Capsules.

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.

Based on the health hazard evaluation by firm, the possibility of adverse event occurrence is remote and no risk has been expected to be imposed to patient. Additionally, all the lots were

packed in 100 and 500 count HDPE bottles, which are dispensed by the pharmacy and dispensing pharmacist can easily detect the wet capsules, if 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 lots 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. If you do not possess any inventory of the lot being recalled, then also please 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 sincerely apologize for any inconvenience this voluntary recall may have caused you.

Yours Sincerely,

Prashant Desai
Vice President – Operations

Zydus Pharmaceuticals (USA) Inc.
73 Route 31 North • Pennington, NJ 08534 • Ph. 609-730-1900 • Fax 609-730-1991

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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: Drug Safety/ Recall Services- Zydus Pharmaceuticals USA Inc.

PRODUCT NAME	***Benzonatate Capsules USP, 100mg - 100's & 500's***
NDC No.	***68382-247-01, 68382-247-05***

NDC NO.	Lot Number	Expiry Date	Bottles Purchased	Bottles Consumed	Bottles in Possession	Bottles to be Returned
68382-247-01	MP2625	02/16				
68382-247-01	MP2626	02/16				
68382-247-01	MP2627	02/16				
68382-247-01	MP4875	04/16				
68382-247-01	MP4876	04/16				
68382-247-01	MP4877	04/16				
68382-247-01	MP4878	04/16				
68382-247-01	MP6482	06/16				
68382-247-01	MP6483	06/16				
68382-247-01	MP6484	06/16				
68382-247-05	MP4878	04/16				
68382-247-05	MP6493	06/16				
68382-247-05	MP6494	06/16				

No. of returns kits/ shipping labels 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_____(e-mail/ fax/ letter/ phone/ other)

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

Zydus Pharmaceuticals (USA) Inc.
73 Route 31 North • Pennington, NJ 08534 • Ph. 609-730-1900 • Fax 609-730-1991

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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 above referenced lots directly from Zydus Pharmaceuticals USA Inc, then please provide details of your wholesaler: _____ (Name, City) from where you purchased this product.

Signature: _____ Date: _____

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