ZyPharma

ZYDUS PHARMACEUTICALS
A GLOBAL GENERIC PHARMACEUTICAL COMPANY

ZyGenerics

Dated: September 24, 2014

URGENT DRUG RECALL

Dear Customer:

This communication is to notify you that Zydus Pharmaceuticals USA Inc., is voluntarily recalling following 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, 200mg	MM8555	09/14	100's	68382-248-01	02/05/2013	02/11/2013
Benzonatate Capsules, 200mg	MM6604	09/14	100's	68382-248-01	01/15/2013	01/17/2013
Benzonatate Capsules, 200mg	MM8551	09/14	100's	68382-248-01	01/17/2013	01/21/2013
Benzonatate Capsules, 200mg	MM8552	09/14	100's	68382-248-01	01/21/2013	01/28/2013
Benzonatate Capsules, 200mg	MM8553	09/14	100's	68382-248-01	01/28/2013	01/29/2013
Benzonatate Capsules, 200mg	MM8554	09/14	100's	68382-248-01	01/29/2013	02/05/2013

Zydus Pharmaceuticals USA inc. has decided to initiate voluntary recall of six lot of the above drug product based on a product complaint that was received from a pharmacist who stated that a technician opened a sealed bottle and poured the contents onto a counting tray. She noticed that one capsule was smaller and discovered a single 100mg Benzonatate capsule mixed in with Benzonatate 200mg 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 an independent consulting firm, the possibility of adverse event occurrence is remote and no risk has been imposed to patient. Additionally, the entire lots were packed in 100 HDPE bottles, which is dispensed by the pharmacy and dispensing pharmacist can easily detect the smaller pill, 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 lot of the drug product under the purview of this recall.

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

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

ZyPharma

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

PRODUCT NAME	***Benzonatate Capsules USP, 200mg***
Lot #	***MM6604, MM8551, MM8552, MM8553, MM8554, MM8555***
NDC No.	***68382-248-01***
Expiry	***09/14***

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

Zydus Pharmaceuticals (USA) Inc.
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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: _____