

Attachment#1

Dated: January 14, 2016

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 at **RETAIL LEVEL**:

Product Name	Lot No.	Expiry	Pack Size	NDC No.	Distribution Start Date	Distribution End Date
Risperidone OD Tablets, 2mg	MP4967	04/16	30's	68382-156-06	Aug 28, 14	Aug 04, 15
Risperidone OD Tablets, 0.5mg	MP6917	06/16	30's	68382-154-06	Oct 09, 14	Jul 14, 15
Risperidone OD Tablets, 0.5mg	MP4965	04/16	30's	68382-154-06	Aug 29, 14	Oct 09, 14
Risperidone OD Tablets, 0.5mg	MP2943	02/16	30's	68382-154-06	Jun 09, 14	Sep 04, 14
Risperidone OD Tablets, 1mg	MP6918	06/16	30's	68382-155-06	Jan 20, 15	Aug 19, 15
Risperidone OD Tablets, 1mg	MP4966	04/16	30's	68382-155-06	Sep 12, 14	Jan 20, 15
Risperidone OD Tablets, 1mg	MP2944	02/16	30's	68382-155-06	Jun 23, 14	Sep 15, 14

Zydus Pharmaceuticals USA Inc. has decided to initiate voluntary recall of the above drug product based on OOS result in retention sample of Risperidone OD Tablet, 2 mg, 30 count bottle (Lot Number MP4967) for Risperidone CIS-N-Oxide impurity during stability testing. As part of firm's impact assessment and based on the trend of this impurity, risk of stability failure in other unexpired lot numbers may be anticipated as mentioned in above table.

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 Health Hazard Evaluation performed by an independent firm, the potential risk to patient population is considered to be minimal as compared to parent molecule. Based on this fact, 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 rxrecalls@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.

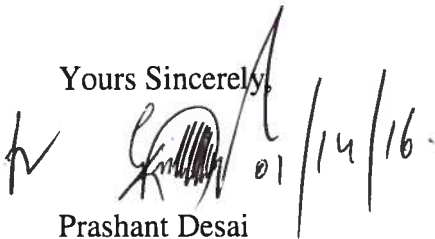
If you have any questions about product safety issue, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779 Option# 2.

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
Sr. Vice President – Technical Operations

PRODUCT RECALL RESPONSE FORM**URGENT DRUG RECALL**

Please complete the required information and fax to **1-817-868-5362**
or email to rxrecalls@inmar.com
To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

Product Name	Lot No.	Expiry	Pack Size	NDC No.
Risperidone OD Tablets 2mg	MP4967	04/16	30's	68382-156-06
Risperidone OD Tablets 0.5mg	MP6917	06/16	30's	68382-154-06
Risperidone OD Tablets 0.5mg	MP4965	04/16	30's	68382-154-06
Risperidone OD Tablets 0.5mg	MP2943	02/16	30's	68382-154-06
Risperidone OD Tablets 1mg	MP6918	06/16	30's	68382-155-06
Risperidone OD Tablets 1mg	MP4966	04/16	30's	68382-155-06
Risperidone OD Tablets 1mg	MP2944	02/16	30's	68382-155-06

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☐ We have identified and notified my customers that were shipped or may have been shipped this product by _____;☐ Attached is the list of customers who received/ may have received this product. Please notify my customers.

Effective Date: - 11/11/15 SOP#SOP-ZUSA-006 SOP Rev#00 Page1 of 2

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

___ Repacker

___ 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: _____