Dr.Reddy's

Dr. Reddy's Laboratories, Inc.
107 College Road East,
Princeton, NJ 08540

URGENT: DRUG RECALL

10/18/2016

Olanzapine Tablets, 2.5mg

MANUFACTURED BY:
Dr. Reddy's Laboratories Ltd.
Bachupally - 500090 India

RECALLED BY:
Dr. Reddy's Laboratories Inc.
107 College Road East,
Princeton, NJ- 08540 USA

Dear Valued Customer:

This is to inform you of a product recall involving:

Olanzapine Tablets, 2.5mg

See enclosed product label.

This voluntary recall has been initiated due to an out-of-specification result obtained for Related Substances Compound C (Impurity 6- N Oxide) during stability testing. No genotoxicity and any other toxicities of the above said impurity in humans could be found in literature, however risk to the patient consuming Olanzapine tablets from the below mentioned batch cannot be ruled out.

The batch lot of the product to be recalled is:

Item Description	NDC	Lot Number	Expiration Date
Olanzapine Tablets, 2.5mg, 30ct	55111-163-30	C500202	12/2016

The product Distribution dates are: March 25 – April 06, 2015

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for batch lot listed above and immediately discontinue distribution and sales of the product lot being recalled. Please quarantine the affected batch lot of this product.

- In addition, if the listed product was further distributed, please identify the customers and notify them immediately of this product recall. The notification to the customers may be expedited by including a copy of this recall notification letter

- Promptly complete the attached recall stock response form even if you have **no** product to return.

Completed Recall Stock Response form can be submitted by any of the below methods:
Fax: 817-868-5362
E-mail: RXrecalls@inmar.com
Mail: Inmar, Attn: Recall Coordinator,
4332 Empire Road Suite 200,
Fort Worth, TX 76155

For questions regarding return of the recalled product please call Inmar at 800-967-5952.

Upon receipt of your Recall Response Form a "Return Kit" will be sent to you. This kit will include:
- Pre-paid shipping label(s)
- Processing labels
- Shipping instructions

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

Your cooperation and prompt response to this notice is much appreciated. If you have Customer Service related questions, please contact Dr. Reddy's Laboratories 866-733-3952 Medical related questions, please contact Dr. Reddy's Laboratories/ DLSS at 888-375-3784

Sincerely,

Douglas Forman
Director, Quality
Dr. Reddy's Laboratories, Inc.

Enclosure(s)
1. Product Label
2. Recall Return Response Form

Dr.Reddy's

RECALL STOCK RESPONSE FORM

RECALL of Olanzapine Tablets, 2.5mg
10/18/2016

VOLUNTARY RECALL – Class TBD

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Company Name _____DEA #_____

DEA # required, if not provided the processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____Telephone #_____

Contact Signature _____Date_____

I have checked my stock and:

_____Do not have any stock of the recalled **items**.

OR

I have quarantined and listed in the box below the qty of recalled units I will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) and will need_____ # of box labels

Item Description	NDC	Lot	Qty returning
Olanzapine Tablets, 2.5mg, 30ct	55111-163-30	C500202	

Wholesalers and Distributors only

☐ I have identified my customers that were shipped or may have been shipped this product. Attached is a list of customers with their contact details who received/may have received this product.

If you did not purchase the product directly from the Manufacturer please complete the below section.

Purchased From: Wholesaler Name _____DEA #_____

City_____ State_____

If you have any questions regarding this form or product return please contact Inmar at 1-800-967-5952 Office hours 9am to 5pm Monday through Friday.

Please fax this form to: 1-817-868-5362 or E-mail: RXrecalls@inmar.com