URGENT: DRUG RECALL

Clonazepam Orally Disintegrating Tablets, USP, 0.125 mg

July 2, 2020

Dear Customer,

This notice is to inform you of a product recall involving:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Clonazepam Orally Disintegrating Tablets, USP 0.125 mg	60 Count	AA84106	57664-783-86	09/2021

See enclosed product labeling.

This recall has been initiated in response to an out of specification result observed during routine stability testing of Related Compounds for the Highest Unknown Impurity. The impurity has been identified as another drug substance (Clozapine) used to manufacture another product at the same facility. Use of this product is unlikely to pose any risk to patient safety.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on January 20, 2020.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your retail customers and notify them at once of this product recall. Your notification to your retail 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. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar, Inc.
4332 Empire Road
South Dock
Fort Worth, TX 76155

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-855-547-4348, Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

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

Aimee Albanese 07-02-2020

Aimee Albanese
Sun Pharmaceutical Industries, Inc.
Associate Director, Cluster Quality Support

Enclosure

For return of affected product, please email rxrecalls@inmar.com or call 1-855-547-4348.

Enclosures:
Clonazepam Orally Disintegrating Tablets, USP, 0.125 mg (60 Count) Bottle Labeling

For return of affected product, please email rxrecalls@inmar.com or call 1-855-547-4348.

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Clonazepam Orally Disintegrating Tablets, USP 0.125 mg	60 Count	AA84106	57664-783-86	09/2021

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the July 2, 2020 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units.

□ Indicate disposition of recalled product:

□ returned (**specify quantity, date and method**)/held for return;

Number of Labels Required for Return to Inmar: _____

□ previously destroyed (**specify quantity, date and method**);

□ I have identified and notified my retail customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or

□ Attached is a list of retail customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? □ Yes □ No
If yes, please explain: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-547-4348.

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Please check the appropriate box(es) to describe your business

□ wholesaler/distributor
□ grocery corporate headquarters
□ repacker
□ pharmacy
□ retailer
□ hospital pharmacies
□ hospital/medical facility
□ Other:

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____City\State: _____

Wholesaler DEA Number: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-547-4348.