November 01, 2018

URGENT DRUG RECALL

Nitrofurantoin 100 mg Capsules

Dear Valued Customer:

The purpose of this letter is to inform you that Sandoz Inc. ("Sandoz") is initiating a Voluntary Recall of six (6) lots of **Nitrofurantoin 100 mg Capsules**. These six (6) lots are being recalled due to the potential presence of unrelated ingredients (i.e., traces of active ingredients of Benazepril, Haloperidol and Perphenazine), which were identified through a manufacturing investigation. Based on a Medical Assessment performed, adverse health consequences are unlikely to occur as a result of this issue.

This Voluntary Recall is being conducted to the **Retail Level (Level B)** with the knowledge of the Food and Drug Administration. All locations which received direct shipments of these lots from Sandoz have been sent a recall notification packet.

Product Name	NDC	Lot Number	Expiration Date	Manufacturer	Distributor
Nitrofurantoin Capsules 100mg (100 Count) - Sandoz Label	0185-0122-01	JB4952	03/2020	Sandoz Inc.	Sandoz Inc.
Nitrofurantoin Capsules 100mg (100 Count) - Sandoz Label	0185-0122-01	JA7322	03/2020		
Nitrofurantoin Capsules 100mg (1000 Count) - Sandoz Label	0185-0122-10	JA7324	03/2020		
Nitrofurantoin Capsules 100mg (100 Count) – North Star Label	16714-439-01	JA7319	03/2020		North Star
Nitrofurantoin Capsules 100mg (100 Count) - North Star Label	16714-439-01	JA7320	03/2020		
Nitrofurantoin Capsules 100mg (100 Count) - North Star Label	16714-439-01	JA7321	03/2020		

Our records indicate that you received shipments of these lots between June 2018 and August 2018. Therefore, please examine your inventory immediately to determine if you have any quantities of these lots.

We ask for your cooperation in taking the following actions:

1. Immediately stop distribution of these lots only and quarantine any quantities of these lots remaining in your control.
2. If you have further distributed these lots, up to and including the **Retail Level,** then please contact these accounts immediately, advise them of the recall and have them return their outstanding recalled stock. Please advise your accounts that this recall is to the **Retail Level**.
3. Conduct a physical count and record this data on the included Business Reply Card and the Packing Slip.
4. **Mail the postage paid Business Reply Card even if you do not have the recalled product in your inventory.**
5. Return the recalled product and the Packing Slip using the prepaid Fed Ex shipping label to the address below:

GENCO Pharmaceutical Services

6101 North 64th Street

Milwaukee, WI 53218

Do not include non-Sandoz items or other Sandoz labeled items in your shipment. All product not associated with this recall will be destroyed and no credit issued. Please report any adverse reactions by calling Sandoz at (800) 525-8747. Customer service agents are available from 8:00AM to 5:00PM (EST), Monday-Friday. Adverse events can also be reported to FDA online at www.fda.gov/medwatch/report.htm. For product or reimbursement questions regarding the lot listed above, please call Sandoz at (800) 525-8747. For questions about the recall process, please call GENCO Pharmaceutical Services at 855-838-5785 between the hours of 7:00 AM to 5:00 PM Monday - Friday (CST). If you have any other questions, please contact your Manager of National Accounts.

We appreciate your immediate attention and cooperation and apologize for any inconvenience caused by this action.

Sincerely,

10/31/2018

Allen Sicley

QA Site Head