SANDOZ A Novartis Division

**Sandoz Inc.**
100 College Road West
Princeton, NJ 08540

November 1, 2018

**URGENT DRUG RECALL**

**Losartan Potassium and Hydrochlorothiazide Tablets**

Dear Valued Customer:

The purpose of this letter is to inform you that Sandoz Inc. ("Sandoz") is initiating a Voluntary Recall of one (1) lot of Losartan Potassium and Hydrochlorothiazide 100mg/25mg. This single lot is being recalled due to the presence of traces of an impurity, NDEA (N-nitrosodiethylamine), identified during defined screening tests of Losartan API (Active Pharmaceutical Ingredient) sourced from an external supplier. Based on a Medical Assessment concluded, a daily intake of 0.019 ppm (0.0019 µg) NDEA (N-nitrosodiethylamine) from Losartan Potassium and Hydrochlorothiazide tablets could represent an increased cancer risk to patients. This is isolated to one specific batch of Losartan Potassium API utilized in the manufacture of Losartan Potassium and Hydrochlorothiazide Tablets, USP subject to this recall.

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 this lot from Sandoz have been sent a recall notification packet.

| Product Name | NDC | Lot Number | Expiration Date | Manufacturer | Distributor |
|---|---|---|---|---|---|
| Losartan Potassium and Hydrochlorothiazide 100mg/25mg (1000 count Tablets) | O781-5207-10 | JB8912 | 06/2020 | Sandoz Inc. | Sandoz Inc. |

Our records indicate that you received shipments of this lot October 2018. Therefore, please examine your inventory immediately to determine if you have any quantities of this lot.

We ask for your cooperation in taking the following actions:

1. Immediately stop distribution of this lot only and quarantine any quantities of this lot remaining in your control.
2. If you have further distributed this lot, 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) 838-5787 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,

Emma Harrington
Executive Director of Quality