Sandoz Inc. Issues Voluntary Nationwide Recall of One Lot of Losartan Potassium and Hydrochlorothiazide Due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)

November 8, 2018

Sandoz Inc. is voluntarily recalling one lot of losartan potassium hydrochlorothiazide tablets, USP 100 mg/25 mg to the consumer level. This product is being recalled due to the trace amount of an impurity, N-nitrosodiethylamine (NDEA) contained in the API losartan, USP manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. Sandoz Inc. Losartan potassium hydrochlorothiazide product is manufactured by Lek Pharmaceuticals dd, Ljubljana, Slovenia. This impurity, which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC). To date, Sandoz Inc. has not received any reports of adverse events related to this lot.

Losartan potassium hydrochlorothiazide tablets, USP are indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. The product can be identified as losartan potassium hydrochlorothiazide, 100 mg/25 mg tablets in 1,000-count plastic bottles, NDC 0781-5207-10, Lot number JB8912; Exp. Date 06/2020. This product was distributed nationwide to distributors. The affected product was not distributed prior to October 8, 2018.

Sandoz Inc. is notifying its distributors by letter via overnight mail and patients by this public notification. Distributors and retailers that have product, which is being recalled, should immediately stop distribution of the identified lot above and quarantine any quantities remaining in your control and return the recalled product to the identified Reverse Distributor.

Patients with questions regarding this recall can contact Sandoz Inc. at 1-800-525-8747 Monday-Friday 8:30 AM – 5:00 PM (EST) or email usdrugsafety.operations@novartis.com. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on losartan potassium hydrochlorothiazide should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using losartan potassium hydrochlorothiazide.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Click Here to Access FDA Alert: Losartan and HCTZ recall.