Clifton Health Department
Food Recall Notification

Public Health
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Food/Drug/Pet Recall: Legacy Pharmaceutical Packaging, LLC

Legacy Pharmaceutical Packaging, LLC is expanding its consumer-level recall of 3 repackaged lots Losartan Tablets USP 50mg to include one additional lot. This recall was prompted due to Torrent Pharmaceuticals LTD issuing a Voluntary Nationwide Recall of Losartan Tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer).

NMBA is a potential human carcinogen. To date, Legacy has not received any reports of adverse events related to this recall.

Losartan Potassium USP is a prescription medication used to treat high blood pressure and congestive heart failure and is packaged in 30ct bottles. The identifying NDC number associated with Legacy's product is as follows:

Losartan Potassium, USP, 50mg NDC 68645-494-54

The affected Losartan Potassium includes 4 repackaged lots numbers (3 initial repackaged lot and 1 expanded repackaged lot) which are listed below:

LEGACY NDC#

Name and Strength

Count

Legacy Lot #

Expiry

68645-494-54 Losartan Potassium Tablets USP 50 mg 30 180190 10/2020
68645-494-54 Losartan Potassium Tablets USP 50 mg 30 180191 10/2020
68645-494-54 Losartan Potassium Tablets USP 50 mg 30 181597 02/2021
68645-494-54 Losartan Potassium Tablets USP 50 mg 30 181598 02/2021

The product can be identified by checking the product name and repackaged lot number on the bottle containing these products.

Losartan Potassium was distributed by pharmacies nationwide. Legacy Pharmaceutical Packaging LLC is notifying its distributors and customers in writing and is arranging/assisting for

return of all recalled products to Inmar Pharmaceutical Services. Instructions for returning recalled products are provided in the recall letter.

Consumers with questions regarding this recall can contact Inmar at 1-877-538-8443, Monday - Friday, 9am - 5pm EST. Consumers should contact their physician or healthcare provider if they have that may be related to taking or using this drug product.

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

.Complete and submit the report Online: www.fda.gov/medwatch/report.htm

.Regular Mail or Fax: Download form 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.