Pharmacy Recalls and Withdraws

Updated: May 31, 2019

Current Recalls -

April 18, 2019

Torrent Pharmaceuticals Limited is expanding its recall for Losartan Potassium Tablets USP and Losartan Potassium/hydrochlorothiazide tablets, USP, to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited

The Recall is expanded to include an additional 36 lots of Losartan potassium Tablets USP and 68 lots of Losartan Potassium/Hydrochlorothiazide Tablets.

The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA). Torrent is only recalling lots of Losartan-containing products that contain N-Methylnitrosobutyric acid (NMBA) above the acceptable daily intake levels released by the FDA.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

April 21, 2019

Alvogen, Inc. is voluntarily recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level. A small number of cartons labeled 12 mcg/h Fentanyl Transdermal System patches contained 50 mcg/h patches. The 50 mcg/h patches that were included in cartons labeled 12 mcg/h are individually labeled as 50 mcg/h. This transdermal system is manufactured by 3M Drug Delivery Systems, St. Paul, MN.

Application of a 50 mcg/h patch instead of a prescribed 12 mcg/h patch could result in serious, life threatening, or fatal respiratory depression. Groups at potential increased risk could include first time recipients of such patches, children, and the elderly. To date, Alvogen Inc. has not received any reports of adverse events related to this issue.

April 24, 2019

Legacy Pharmaceutical Packaging, LLC is recalling 40 repackaged lots of Losartan Tablets USP 25mg, 50mg, and 100mg to the consumer level. This recall was prompted due to Camber Pharmaceuticals, Inc. 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.

May 3, 2019

Vivimed Life Sciences Pvt Ltd (Vivimed) is recalling 19 lots of Losartan Potassium Tablets USP 25 mg, 50 mg, and 100 mg to consumer level. Due to the detection of an impurity – N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) that is above the US Food & Drug Administration's interim acceptable exposure limit of 9.82 ppm. Based on the available information, the risk of developing cancer in a few patients following long-term use of the product containing high levels of the impurity NMBA cannot be ruled out.

This product is made by Vivimed at its Plant in Alathur, Chennai, India and Distributed by Heritage Pharmaceuticals Inc, East Brunswick NJ (Heritage). To date, neither Vivimed nor Heritage has received any reports of adverse events related to this recall.

If you would like additional information on current or past recalls please visit the FDA Drug Recall website:

https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls