NJLINCS Health Alert Network
Public Health Info
Distributed by the New Jersey Department of Health

Subject: Food and Drug Recalls
Date: 4/23/2019; 15:38:29
Message#: 103791-4-23-2019-PHIN

Please review the following message from Alan Talarsky, Environmental Scientist 1, Public Health and Food Protection Program, NJDOH regarding the following Class 1 Recalls issued by the U.S. Food and Drug Administration:

1. Weis Markets has issued a recall for its Weis Quality Banana Pudding Ice Cream (48oz) since the product's ingredient label fails to list an egg allergen due to a supplier error. People who have an allergy or severe sensitivity to eggs run the risk of serious or life-threatening allergic reaction if they consume these products. There have been no reports of illness from customer's consuming this product to date.

This product has been removed from sale. It was sold in 200 Weis Markets' stores in Pennsylvania, Maryland, Virginia, New Jersey, New York, Delaware and West Virginia. The ice cream is packaged in a round container with a UPC of 041497-01305. All lot codes are affected. An example of the label has been included with this release. Customers who have purchased this product may return it for a full refund.

Customers requiring additional information may contact Weis Customer Service at 1-866-999-9347 Monday through Friday 8am-5pm.

****

2. 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, USP

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.

Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Losartan potassium and hydrochlorothiazide tablets, USP is used to treat hypertension and

hypertensive patients with Left Ventricular Hypertrophy.

Patients who are taking Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The product/lots included in the expanded recall are listed below in the second table. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

The full list of recalled lots may be accessed at this weblink: https://www.fda.gov/Safety/Recalls/ucm636296.htm?utm_campaign=Updated%3A%20Torrent%20Pharmaceuticals%20Limited%20Expands%20Voluntary%20Recall%20of%20Losartan%20Potassium%20Tablets&utm_medium=email&utm_source=Eloqua

Losartan potassium tablets, USP and Losartan potassium/ hydrochlorothiazide tablets, USP were distributed nationwide to Torrent's wholesale distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with medical questions regarding this recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at:

. 1-800-912-9561 (live calls received 8:00 am - 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week).
. Medinfo.Torrent@apcerls.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general questions regarding the return of this product should be directed to Qualanex at 1- 888-280-2040 (live calls received 8 am - 9:00 pm Eastern Time). 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 www.fda.gov/MedWatch/getforms.htm
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

****

3. 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.

The product is indicated for the management of pain in opioid tolerant patients and is packaged in primary cartons of five individually wrapped and labeled pouches. The affected Fentanyl Transdermal System lots include:

Lot 180060 of Fentanyl Transdermal System, 12 mcg/h, expiration date 05/2020.
Lot 180073 of Fentanyl Transdermal System, 12 mcg/h, expiration date 06/2020.
The mislabeled product is packaged in a 12 mcg/h primary carton. These lots of Fentanyl Transdermal System were distributed Nationwide to the pharmacy level.
See images example for lot 180073.

Alvogen Inc. is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. Pharmacies are requested not to dispense any product subject to this recall. Patients that have product subject to this recall should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to point of purchase for replacement.

Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to pharmacovigilance@alvogen.com from Monday to Friday from 9:00 am to 5:00 pm EST. Consumers should contact their physician or health care provider if they have experienced any problems 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.

****

No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

****

For all recalls - http://www.recalls.gov/recent.html