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

Subject: Food and Drug Recalls
Date: 7/18/2018; 10:42:34
Message#: 103634-7-18-2018-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 and the U.S. Department of Agriculture:

1. Utz® Quality Foods, LLC., is voluntarily recalling select expiration dates of Utz® Carolina Style Barbeque Potato Chips due to undeclared soy allergen. This recall was initiated after learning a certain number of packages were mislabeled. People who have an allergy or severe sensitivity to soy run the risk of serious or life-threatening allergic reaction if they consume these products.

The items subject to this voluntary recall were distributed to retail outlets in the following states: AL, AR, CO, CT, DC, DE, FL, GA, IL, IN, KY, LA, MA, MD, ME, MS, NC, NE, NH, NJ, NY, OH, PA RI, SC, TN, TX, UT, VA, VT, WV

NO ILLNESSES ASSOCIATED WITH THIS VOLUNTARY RECALL HAVE BEEN REPORTED TO DATE.

The items and related expiration dates being voluntarily recalled include:

Item Description

UPC

Expiration Date
FROM

Expiration Date
TO

Utz 2.875 oz. Carolina Style Barbeque Potato Chips 0-41780-00153-5 October 6th October 20th
Utz 7.5 oz. Carolina Style Barbeque Potato Chips 0-41780-00049-1 August 18th October 27th

Please see below for an example of reading the expiration dates and UPC code:

No other Utz® products are being recalled.

Consumers are urged NOT eat the products subject to this voluntary recall. Consumers who purchased the recalled product may return it to the store where it was purchased for a full refund or exchange, or they may simply discard it.

For further information please contact the Customer Care Team: Email: customerservice@utzsnacks.com or, call 1-800-367-7629 Monday through Friday 8:30 am to 5:00 pm Eastern Time Retailers and wholesalers should check their inventories and shelves to confirm that none of the products are present or available for purchase by consumers.

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2. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is recalling all lots of Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg: and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg to the retail level. This product recall is due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer - Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

The products are indicated for the treatment of hypertension.

The exposure to the impurity N-nitrosodimethylamine (NDMA) that was detected in valsartan product line presents an unacceptable carcinogenic risk to the intended patient population. To date, Prinston Pharmaceutical Inc. has not received any reports of adverse events related to this recall.

Product

NDC Code

Lot Number

Expiry Dates

Distribution Date

VALSARTAN TABLETS 40MG 30CT 43547-367-03 All lots From Jul 18 to Jan 20 Oct 2015 - Jun 2018
VALSARTAN TABLETS 80MG 90CT 43547-368-09 All lots From Jul 18 to Jan 20 Oct

2015 - Jun 2018
VALSARTAN TABLETS 160MG 90CT 43547-369-09 All lots From Jul 18 to Jan 20 Oct 2015 - Jun 2018
VALSARTAN TABLETS 320MG 90CT 43547-370-09 All lots From Jul 18 to Jan 20 Oct 2015 - Jun 2018
VALSARTAN/HCTZ 80MG/12.5MG 90CT TABLETS 43547-311-09 All lots From Jul 18 to Jan 20 Jun 2016 - Jun 2018
VALSARTAN/HCTZ 160MG/12.5MG 90CT TABLETS 43547-312-09 All lots From Jul 18 to Jan 20 Jun 2016 - Jun 2018
VALSARTAN/HCTZ 160MG/25MG 90CT TABLETS 43547-313-09 All lots From Jul 18 to Jan 20 Jun 2016 - Jun 2018
VALSARTAN/HCTZ 320MG/12.5MG 90CT TABLETS 43547-314-09 All lots From Jul 18 to Jan 20 Jun 2016 - Jun 2018
VALSARTAN/HCTZ 320MG/25MG 90CT TABLETS 43547-315-09 All lots From Jul 18 to Jan 20 Jun 2016 - Jun 2018

The lot number and expiry date information can be found on the manufacturer's unit.

Retail pharmacies in possession of any unused products: Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg: and Valsartan-HCTZ Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg, within expiry dates from Jul 2018 to Jan 2020 should immediately return the product by following the instructions below:

.Please contact Solco Customer Service at 1-866-931-9829, Option 5, Monday through Friday (9am to 5pm EST) or email or fax to: customerservice@solcohealthcare.com: 1-866-931-0709, for the Product Return.
.A call tag, a pre-printed, pre-paid return label will be provided to you for product return: return is free of charge.
.Return products to:
DLSS (Dohmen Life Science Services) Attn: Returns Department
4580 S. Mendenhall, Memphis, TN 38141

Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products. Pharmacies and wholesalers that received the impacted products will receive a letter as well as a copy of this press release with their recall notification information.

If you have any questions regarding this recall, please call 1-866-931-9829, Option 5, between the hours of 9:00 a.m. to 5:00 p.m. EST Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product. Additional information regarding this recall affected products' lots and expiry dates can be found at http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffactedLots.pdf or to download at

http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffactedLots.xlsx

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.

This Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

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3. Teva Pharmaceuticals USA today confirmed a voluntary recall to the consumer / user level of 29 lots of single and 51 lots of combination valsartan medicines distributed under the Actavis label in the U.S. due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceutical. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, TEVA has not received any reports of adverse events related to this recall. Valsartan is used for the treatment of hypertension (high blood pressure) and for the treatment of heart failure. It is also indicated as a treatment for left ventricular failure and left ventricular dysfunction following myocardial infarction. In combination with hydrochlorothiazide, it is used in the treatment of hypertension.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan 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.

The products subject to recall and listed below are packed in bottles. These lots were distributed Nationwide to Teva's Direct Accounts (Wholesale/Distributor/Retail/Repackagers/VA Pharmacy, et. al).

The full list of lots can be viewed at the following webpage:
https://www.fda.gov/Safety/Recalls/ucm613729.htm?utm_campaign=Teva%20Pharmaceuticals%20USA%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Valsartan&utm_medium=email&utm_source=Eloqua

Teva is notifying its Direct Accounts by FedEx Overnight mailing to immediately

discontinue distribution of the specific lots being recalled and to notify their sub-accounts of this product recall and making arrangements for impacted product to be returned to Inmar. Instructions for returning recalled products and crediting are given in the recall letter.

Customers and patients with Medical-related Questions, information about an Adverse Event or other questions about the Teva product's being recalled should contact Teva's Medical Information by phone at: 888-838-2872, then option 3.

. Live calls are received Monday-Friday, 9:00AM-5:00PM Eastern Time with Voicemail available 24 hours/day, 7 days/week or email druginfo@tevapharm.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to Teva directly at 888- 838-2872 or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

o Complete and submit the report Online: www.fda.gov/medwatch/report.htm
o Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm

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

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4. As a precautionary measure, the distribution firm, Major Pharmaceuticals, is issuing a nationwide voluntary recall of all lots within expiry of Valsartan which were supplied by Teva Pharmaceuticals and labeled as Major Pharmaceuticals.

Major Pharmaceuticals is partnering with the Food and Drug Administration (FDA) to notify customers who may be in possession of Valsartan tablets supplied by Teva Pharmaceuticals. Please see the below list of affected products and lot numbers.

The products subject to this recall were distributed nationwide to wholesale and retail facilities, including hospitals and pharmacies. Through recent communication with FDA, Major Pharmaceuticals learned of a potential issue with the active pharmaceutical ingredient in Valsartan supplied by Teva Pharmaceuticals which may contain the probable carcinogen N- nitrosodimethylamine (NDMA). Major Pharmaceuticals as a distribution firm, is recalling all lots within expiry of Valsartan supplied by Teva Pharmaceuticals. Major Pharmaceuticals has not received any reports of adverse events related to this recall to date.

Valsartan is a prescription medication that is commonly used to treat high blood pressure and heart failure. The product was distributed as unit dose blisters with 100 tablets per carton. The distribution firm is notifying distributors and other customers by recall letter and arranging for return of all recalled products. Consumers should contact their doctor for further guidance and potential change of treatment before they stop

taking this product. Pharmacies, and healthcare facilities that have product being recalled should stop using and dispensing the product immediately.

Consumers with questions regarding this recall should contact Major Pharmaceuticals Customer Support at 1-800-616-2471, Option #1 available Monday through Friday 8 a.m. - 8 p.m. EST. Consumers can contact their physician or healthcare provider if they have additional questions about this 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 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

This recall is being conducted with the full knowledge of the U.S. FDA.

MAJOR PHARMACEUTICALS

Product Description

NDC Number

Item Number

Lot Number

Expiration Date

Valsartan 80mg Tablets, USP 0904-6594-61 302086 T01795 05/2019
T01807 05/2019
T01712 02/2019
T01625 02/2019
T01596 02/2019
T01500 02/2019
T01466 07/2018
T01270 07/2018
Valsartan 160mg Tablets, USP 00904-6595-61 302087 T01646 05/2019
T01788 05/2019
T01668 05/2019
T01524 02/2019

T01269 07/2018

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5. Smithfield Packaged Meats Corp., doing business as Stefano Foods., a Charlotte, N.C. establishment, is recalling approximately 24,048 pounds of pepperoni five cheese calzones that may be contaminated with extraneous materials, specifically pieces of hard, sharp, clear plastic, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced.

The not fully cooked pepperoni five cheese calzone products were produced on May 23, 2018. The following products are subject to recall:

. 8-oz. deli tray of "Stefano's Calzone PEPPERONI FIVE CHEESE STUFFED WITH PEPPERONI AND A FIVE CHEESE BLEND," with "Lot Code 14318B" on the individual packages and "USE BY DATE 1/18/2019" on the product cases.

The products subject to recall bear establishment number "EST. M-19140" inside the USDA mark of inspection. These items were shipped to retail stores nationwide.

The problem was discovered after several consumers contacted Stefano Foods about the problem. On July 16, 2018, the company notified FSIS.

One consumer reported experiencing a small oral laceration during consumption of the product. Anyone concerned about an injury or illness should contact a healthcare provider.

FSIS is concerned that some product may be frozen and in consumers' and retailers' freezers. Consumers and retailers who have purchased these products are urged not to consume them. These products should be thrown away or returned to the place of purchase.

FSIS routinely conducts recall effectiveness checks to verify recalling firms notify their customers of the recall and that steps are taken to make certain that the product is no longer available to consumers. When available, the retail distribution lists will be posted on the FSIS website at www.fsis.usda.gov/recalls.

Consumers with questions about the recall can contact Wendy Johnson, Consumers Affairs Manager, Smithfield Packaged Meats Corp., at WJohnson@Smithfield.com or 1-877-933-4625. Members of the media with questions about the recall can contact Diana Souder, Director of Corporate Communications, Smithfield Packaged Meats Corp., at DSouder@smithfield.com or (757) 357-1675.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov or via smartphone at m.askkaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available

in English and Spanish and can be reached from 10 a.m. to 6 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day. The online Electronic Consumer Complaint Monitoring System can be accessed 24 hours a day at: http://www.fsis.usda.gov/reportproblem.

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

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