NJLINCS Health Alert Network
Public Health Info
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Subject: Food and Drug Recalls
Date: 5/14/2019; 14:54:42
Message#: 103804-5-14-2019-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. Deshi Distributors LLC. of Jamaica, NY, is recalling its 3.5 oz, 7 oz and 14 oz packages of Deshi "Golden Raisins" because they contained undeclared sulfites. Consumers who have severe sensitivity to sulfites run the risk of serious or life-threatening allergic reactions if they consume this product.

The Golden Raisins with undeclared sulfites was distributed in New York, New Jersey, Pennsylvania, and Michigan and through delivery to retail stores.

The product comes in a 3.5 oz, 7 oz. and 14 oz. clear plastic package. UPC codes of Deshi Golden Raisin products are as follows: 3.5 oz is 691035359586: 7 oz. is 691035360179: and 14 oz. is 691035360483.

No illness or allergic reactions involving this product have been reported to date.

The recall was initiated after routine sampling by New York State Department of Agriculture and Markets Food Inspector and subsequent analysis by Food Laboratory personnel revealed the presence of sulfites in the 7 oz. packages of Deshi "Golden Raisin" which were not declared on the label. The same raisins were packaged in 3.5 oz and 14 oz packages and are included in this recall.

Consumers who have purchased 3.5 oz, 7 oz and 14 oz packages of Deshi "Golden Raisins" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 718-291-1205 from 9 am to 5 pm Eastern Time.

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2. Novartis announced a voluntary recall of three lots of Promacta (eltrombopag) 12.5 mg for oral suspension to the consumer level. The oral suspension lots are being recalled because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site.

Promacta tablets in 12.5 mg, 25 mg, 50 mg and 75 mg strengths are not impacted by this recall and are not manufactured in the same facility.

Peanut is a known food allergen. Potential cross contamination with peanut flour, even in small traces, can lead to hypersensitivity reaction in a population of patients with an unknown or known sensitivity to peanut antigen, including a medically significant anaphylactic reaction, which can be fatal.

To date, Novartis has not received any reports or adverse events for this recall.

Promacta 12.5 mg for oral suspension is indicated for the treatment of certain adult and pediatric patients with chronic immune thrombocytopenia, certain adult patients with hepatitis C-associated thrombocytopenia, and certain adult and pediatric patients with severe aplastic anemia who have not received prior immunosuppressive therapy or had an insufficient response to immunosuppressive therapy. See promacta.com for full prescribing information.

Promacta 12.5 mg for oral suspension was distributed nationwide through specialty pharmacies. Novartis is notifying its distributors and customers by letter and asking them to check for impacted product and to return unused product through directions provided in the recall letter. The affected product name, including the lot numbers and expiration dates, include:

Impacted Promacta 12.5 mg for Oral Suspension Lot Numbers:

Product Description

NDC Number on Carton

NDC Number on Packet

Lot Number

Expiration Date

Distribution Dates

Promacta for Oral Suspension 0078-0972-61 0078-0972-19 8H57901589 09/2020 1/2/19 - 2/11/19
Promacta for Oral Suspension 0078-0972-61 0078-0972-19 9H57900189 12/2020 2/11/19 - 4/17/19
Promacta for Oral Suspension 0078-0972-61 0078-0972-19 9H57900289 12/2020 3/6/19 - 4/2/19

Consumers who have impacted product with these lot numbers and NDC numbers in their homes should contact 1-866-918-8772 (8:00 AM - 5:00 PM EST, Monday through

Friday) for instructions on how to return recalled product. For all additional questions, please contact Novartis at 1-888-NOW NOVA (8:30 AM - 5:00 PM EST, Monday through Friday).

Consumers should stop taking Promacta 12.5 mg oral suspension and consult with their healthcare provider. 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.

Pharmacies that have impacted product with these lot numbers and NDC numbers should contact 1-866-918-8772 (8:00 AM - 5:00 PM EST, Monday through Friday) for instructions for return of recalled product.

Healthcare professionals with questions can contact Novartis Medical Information at 1-844-ONC-INFO (1-844-622-4636) or at USOncology.MedInfo@novartis.com.

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
.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.

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No action is required of local health departments at this time for either 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.

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