

NJLINCS Health Alert Network
Public Health Info

Distributed by the New Jersey Department of Health

Subject: Food and Drug Recalls
Date: 6/1/2018; 09:39:35
Message#: 103610-6-1-2018-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. Apotex Corp. is voluntarily recalling one (1) lot of Fluticasone Propionate Nasal Spray, USP, 50 mcg per spray, 120 Metered Sprays, to the consumer level. The Fluticasone Propionate Nasal Spray USP 50 mcg per spray 120 Metered Sprays has been found to contain small glass particles. The glass particles could block the actuator and impact the functionality of the pump. The issue was discovered through a customer complaint.

Risk Statement: There is a potential for patients to be exposed to the glass particles and mechanical irritation cannot be ruled out. Local trauma to the nasal mucosa might occur with use of the defective product. To date, Apotex Corp. has not received any reports of adverse events related to recall.

Fluticasone Propionate Nasal Spray USP 50 mcg per spray 120 Metered Sprays is indicated for the treatment of seasonal and perennial allergic rhinitis and for the management of sinus pain and pressure associated with allergic rhinitis in patients 4 to 17 years of age. The affected Fluticasone Propionate Nasal Spray USP 50 mcg per spray 120 Metered Sprays can be identified by the information in the table below: and on the product label:

NDC

Lot
Number

Expiration
Date

Strength

Configuration/Count

60505-0829-1 NJ4501 07/2020 50 mcg per spray
120 Metered Sprays Carton containing 1 Bottle of 50mcg per spray 120 Metered Sprays

The affected Fluticasone Propionate Nasal Spray, USP, 50 mcg per spray, 120 Metered Sprays was distributed nationwide to wholesalers and distributors.

Apotex Corp. has notified wholesalers/distributor by recall letter to arrange for return of any recalled product.

Consumers/wholesalers/retailers/hospitals/institutions with an existing inventory of the lot subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For additional assistance, call GENCO Pharmaceutical Services, a subsidiary of FedEx Supply Chain (GENCO) at 1- 877-475-5863 (7:00am - 5:00pm, CST Monday thru Friday), to arrange for return of the product.

Customers with questions regarding this recall can contact Apotex Corp. by phone-number 1-800-706-5575 (8:30am - 5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com. Customers should contact their physician or healthcare 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 www.fda.gov/MedWatch/getforms.htm or call 1-800-FDA-1088 to request form, then complete and return address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

2. Ruiz Food Products, Inc., a Denison, Texas establishment, is recalling approximately 50,706 pounds of frozen breakfast burritos that may be contaminated with extraneous material, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced.

The frozen cook and serve breakfast burritos were produced on March 3, 2018. The following products are subject to recall:

.3.38-lb. plastic wrapped packages containing 12 Count, 4.5-ounce individually wrapped frozen "EL MONTEREY SIGNATURE BURRITOS, EGG, SAUSAGE, CHEESE & POTATO" with lot code 18062 and 18063, and a best if used date of 3/3/2019 or 3/4/2019.

The products subject to recall bear establishment number "EST. 17523A" on the back of

the packaging. These items were shipped to retail locations nationwide.

The problem was discovered after the company received complaints from consumers who reported finding white, semi-rigid plastic pieces in the product.

There have been no confirmed reports of adverse reactions due to consumption of these products. Anyone concerned about an injury or illness should contact a healthcare provider.

FSIS is concerned that some product may be in consumers' freezers. Consumers 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.

Consumers with questions about the recall should contact the company's consumer line at 800-772-6474. Members of the media with questions can contact Pat Summers, Communications Manager, at 559-285-1100.

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>

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

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