Enforcement Report - Week of October 20, 2021

Class I Drugs Event

Event ID:
88764

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/24/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/14/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Eli Lilly & Company
839 S Delaware St
Indianapolis IN United States

Distribution Pattern:
Nationwide with the USA and Puerto Rico; Canada, Argentina, Costa Rica, Mexico

Associated Products

Product Description:
Glucagon Emergency Kit for Low Blood Sugar, Glucagon for Injection, 1 mg per vial; Diluent for Glucagon, 1 mL syringe. Rx only, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285; Glucagon, NDC: 0002-8031-01

Product Quantity:
19,174 syringes

Reason for Recall:
SUBPOTENT DRUG: Vial contained a liquid substance, instead of the expected powder substance. There was also a lack of full drug effect upon administration.

Recall Number:
D-0009-2022

Code Information:
Lot #: D239382D, Exp. Date April 2022

Class II Drugs Event

Event ID:
88758

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/08/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
SSM Health Care St. Louis DBA SSM St. Clare Health Center
1015 Bowles Ave
Fenton MO United States

Distribution Pattern:
MO

Associated Products

Product Description:
Potassium Chloride 40 mEq in 0.9% Sodium Chloride 270 mL NS, 250 mL bag, Rx Only, SSM Health Care Corporation, 1015 Bowles, Fenton, MO. NDC 60652-6429-1

Product Quantity:
385 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0007-2022

Code Information:
Lot 210806-015, exp 11/4/2021

Class II Drugs Event

Event ID:
88759

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/08/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Inc.
2 Tower Center Blvd Ste 1102
East Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Potassium Chloride Extended-Release Tablets, USP 10 mEq (750 mg), 500 Tablets, Rx Only, Manufactured by: Strides Shasun Limited, Bengaluru - 562106, India, Distributed by: Strides Pharma In., East Brunswick, NJ 08816, NDC 64380-861-07.

Product Quantity:
1813 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0006-2022

Code Information:
Lot 7240840A, exp. 12/31/2021