Enforcement Report - Week of May 25, 2022

Class I Drugs Event

Event ID:
89879

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/13/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Plastikon Healthcare LLC
3780 Greenway Cir
Lawrence KS United States

Distribution Pattern:
Distributed in Indiana for further distribution in the USA.

Associated Products

Product Description:
MILK OF MAGNESIA USP, (Magnesium Hydroxide), 2400 mg/30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC 0904-6846-73.

Product Quantity:
14,100 Unit Dose cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0867-2022

Code Information:
Lot: 20024A, 20025A, EXP Mar 2022

Product Description:
Magnesium Hydroxide 1200mg, Aluminum Hydroxide 1200mg, Simethicone 120mg, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distribute by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6838-73.

Product Quantity:
23,300 Unit Dose cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0868-2022

Code Information:
Lot: 21067A, EXP Jun 2023

Class I Drugs Event

Event ID:
89976

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/19/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cardinal Health Inc.
7000 Cardinal Pl
Dublin OH United States

Distribution Pattern:
NM only

Associated Products

Product Description:
Humalog KwikPen, Insulin lispro injection, U-100, 100 units per mL, 5x3 mL Prefilled Pens per box, Marketed by Lilly USA, LLC, Indianapolis, IN 46285, Box NDC 0002-8799-59, Pen NDC 002-7516-59

Product Quantity:
1 box

Reason for Recall:
TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions due to inclement weather.

Recall Number:
D-0882-2022

Code Information:
Unknown

Class II Drugs Event

Event ID:
89879

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/13/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Plastikon Healthcare LLC
3780 Greenway Cir
Lawrence KS United States

Distribution Pattern:
Distributed in Indiana for further distribution in the USA.

Associated Products

Product Description:
Acetaminophen Oral Solution, USP 650mg/ 20.3 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6820-76.

Product Quantity:
121,800 Unit Dose cups

Reason for Recall:
CGMP Deviations: Failure to properly investigate failed microbial testing.

Recall Number:
D-0869-2022

Code Information:
Lot: 20040A, EXP May 2022

Product Description:
MILK OF MAGNESIA USP, (Magnesium Hydroxide), 2400 mg/30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC 0904-6846-73.

Product Quantity:
5,400 Unit Dose cups

Reason for Recall:
CGMP Deviations: Failure to properly investigate failed microbial testing.

Recall Number:
D-0870-2022

Code Information:
Lot: 20041A, EXP May 2022

Product Description:
Magnesium Hydroxide 1200mg, Aluminum Hydroxide 1200mg, Simethicone 120mg, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6838-73.

Product Quantity:
106,400 Unit Dose cups

Reason for Recall:
CGMP Deviations: Failure to properly investigate failed microbial testing.

Recall Number:
D-0871-2022

Code Information:
Lot: 20042A, 20043A, 20045A, 20046A, 20047A, EXP May 2022

Class II Drugs Event

Event ID:
89976

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/19/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cardinal Health Inc.
7000 Cardinal Pl
Dublin OH United States

Distribution Pattern:
NM only

Associated Products

Product Description:
Trulicity (dulaglutide) injection, 1.5 mg/0.5mL once weekly, 4 Single-Dose Pens, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 00002-1434-80

Product Quantity:
1 box

Reason for Recall:
TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions due to inclement weather.

Recall Number:
D-0883-2022

Code Information:
Lot #: D482749A, Exp: 10/15/2023.

Product Description:
Trulicity (dulaglutide) injection, 0.75 mg/0.5mL once weekly, 4 Single-Dose Pens, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 00002-1433-80

Product Quantity:
1 box

Reason for Recall:
TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions

Recall Number:
D-0884-2022

Code Information:
Lot #: D484557A, Exp: 10/25/2023.

Class II Drugs Event

Event ID:
90064

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/16/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Accupril (Quinapril HCl Tablets) 10 mg, 90 Tablets Rx only NDC 0071-0530-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017

Product Quantity:
2079 bottles

Reason for Recall:
CGMP Deviations: Contains N-nitrosoquinapril above the acceptable limits.

Recall Number:
D-0872-2022

Code Information:
Lot: DR9639 Exp. MAR 31 2023

Product Description:
Accupril (Quinapril HCl Tablets) 20 mg, 90 Tablets, Rx only NDC 0071-0532-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017

Product Quantity:
10,304 bottles

Reason for Recall:
CGMP Deviations: Contains N-nitrosoquinapril above the acceptable limits.

Recall Number:
D-0873-2022

Code Information:
Lots: DX8682 Exp. MAR 31 2023; DG1188 Exp. MAR 31 2022

Product Description:
Accupril (Quinapril HCl Tablets) 40 mg, 90 Tablets, Rx only NDC 0071-0535-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017

Product Quantity:
8346 bottles

Reason for Recall:
CGMP Deviations: Contains N-nitrosoquinapril above the acceptable limits.

Recall Number:
D-0874-2022

Code Information:
Lots: DX6031 Exp. MAR 31 2023; CK6260 Exp. MAY 31 2022

Class II Drugs Event

Event ID:
90094

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/16/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed nationwide, including Puerto Rico.

Associated Products

Product Description:
GaviLyte -C (Polyethylene Glycol 3350, 240 g) and electrolytes for Oral Solution, USP with flavor pack NDC# 43386-060-19

Product Quantity:
26,910 bottles

Reason for Recall:
Failed Stability Specification

Recall Number:
D-0875-2022

Code Information:
Lot # S001132, exp. date July 2022 NDC # 43386-060-19

Class III Drugs Event

Event ID:
90062

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Monarch PCM, LLC
7333 Jack Newell Blvd N Ste 100
Fort Worth TX United States

Distribution Pattern:
TN only

Associated Products

Product Description:
Phenobarbital Elixir, USP 20 mg/5 mL, 1 Pint (473 mL) bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC Tampa, FL 33624, NDC 69367-172-16

Product Quantity:
15,730 bottles

Reason for Recall:
Does Not Meet USP or OTC Monograph: Product exceeds USP specification for alcohol content

Recall Number:
D-0878-2022

Code Information:
Lot #: 20FP1569 Exp. Date 08/2022; 21FP1674 Exp. Date 02/2023; 21FP1831 Exp. Date 08/2023

Class III Drugs Event

Event ID:
90114

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sirolimus Oral Solution, 1 mg/mL, 60 mL bottle, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326, NDC 60505-6197-2

Product Quantity:
2353 bottles

Reason for Recall:
Failed Dissolution Specifications: Sirolimus Oral Solution recalled due to lot RZ1598 exceeded the specification limit at the 14-month timepoint.

Recall Number:
D-0881-2022

Code Information:
Lot: RZ1598, exp. date 02/2023

Class III Drugs Event

Event ID:
90124

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/18/2022

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Bestco LLC
288 Mazeppa Rd
Mooresville NC United States

Distribution Pattern:
CA, ID, PA, OK

Associated Products

Product Description:
Open Nature Cough Drops Menthol-Cough Suppressant/Oral Anesthetic Peppermint Naturally Flavored, packaged in Bags of 30 lozenges, Distributed By Lucerne Foods, Inc. P.O. Box 99, Pleasanton, CA 96566-0009, UPC 0 79893 41266 5

Product Quantity:
2038 bags

Reason for Recall:
Subpotent drug: Low OOS for menthol content at the three month room temperature.

Recall Number:
D-0879-2022

Code Information:
Lot #: 100010885, Exp 11/2024

Class III Drugs Event

Event ID:
90191

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nitrofurantoin Capsules, USP (Monohydrate/Macrocrystals), 100 mg, 100 Capsules (10 x 10), 10-count blisters per card, 10 cards per carton, Unit Dose NDC 68084-446-11, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC: 68084-446-01

Product Quantity:
1603 cartons

Reason for Recall:
Failed Dissolution Specifications: Nitrofurantoin Capsules recalled due to dissolution failure at 0-time of the repackaged lot. Drug release results were above specification at 0-time.

Recall Number:
D-0880-2022

Code Information:
Lot # 1003829, Exp date 1/31/23