Enforcement Report - Week of November 15, 2023

Class I Drugs Event

Event ID:
93124

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/02/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/09/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the US and Puerto Rico. The products were not distributed to government accounts or foreign consignees.

Associated Products

Product Description:
4.2% Sodium Bicarbonate Injection, USP 5 mEq/10 mL (0.5mEq/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Hospira Inc., Lake Forest, IL 60045, NDC 0409-5534-24

Product Quantity:
24,900 vials

Reason for Recall:
Presence of Particulate Matter: identified as glass.

Recall Number:
D-0100-2024

Code Information:
Lot#: GJ5007, Exp. 8/1/2024

Product Description:
1% Lidocaine HCl Injection, USP, 50mg/5mL(10mg/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Distributed by Hospira Inc., Lake Forest, IL 60045, NDC 0409-4904-11

Product Quantity:
21,390 vials

Reason for Recall:
Presence of Particulate Matter: identified as glass.

Recall Number:
D-0101-2024

Code Information:
Lot#: 42290DK, Exp. 6/1/2024

Product Description:
2% Lidocaine HCl Injection, USP, 100mg/5mL(20mg/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Distributed by Hospira Inc., Lake Forest, IL 60045, NDC 0409-4903-11

Product Quantity:
3,200 vials

Reason for Recall:
Presence of Particulate Matter: identified as glass.

Recall Number:
D-0102-2024

Code Information:
Lot#: GH6567, Exp. 7/1/2024

Class II Drugs Event

Event ID:
89016

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
11/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/04/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAR Sterile Products LLC
870 Parkdale Rd
Rochester MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Buprenorphine HCl, Injection, 0.3mg/mL, For Intramuscular or Intravenous Use, Rx Only, 1mL Single Dose Vial, (supplied in packages of 5 vials) Distributed by Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC: 42023-179-05

Product Quantity:

Reason for Recall:
Crystallization: presence of white, crystalline product agglomeration observed in 2 vials during annual inspection of retain samples.

Recall Number:
D-0087-2024

Code Information:
Lot No: 343716, Exp. Date: 11/2021; Lot No: 350565, Exp. Date: 07/2022; Lot No: 26921, Exp. Date: 07/2022; Lot No: 36227, Exp. Date: 02/2023

Class II Drugs Event

Event ID:
93219

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Deferasirox Tablets for Oral Suspension, 500mg, 30-count bottle, Rx only, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-496-30

Product Quantity:
5,856 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0095-2024

Code Information:
Lot #: 17220063, Exp 12/2023; 17220396, 17220397, Exp 01/2024; 17220965, Exp 04/2024; 17221187, 17221523, Exp 07/2024; 17221793, 17221794, 17221801, Exp 08/2024

Class II Drugs Event

Event ID:
93225

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/03/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Montelukast Sodium Tablets, USP 10 mg, Rx Only, 1000 count bottle, Distributed by: Dr. Reddy's Laboratories., Princeton, NJ 08540, Made in India, NDC# 55111-725-10.

Product Quantity:
1,656 bottles

Reason for Recall:
Presence of Foreign Tablet(s)/Capsule(s): A foreign tablet was found in a bottle of Montelukast Sodium Tablets, USP 10mg, identified as metoprolol 25 mg.

Recall Number:
D-0086-2024

Code Information:
Lot # C2305569, Exp. date 03/31/2026

Class II Drugs Event

Event ID:
93227

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

10/04/2023

Center Classification Date:
11/07/2023

Recalling Firm:
MEDLINE INDUSTRIES, LP - Northfield
3 Lakes Dr
Northfield IL United States

Distribution Pattern:
Nationwide

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Clinical TREAT Antifungal Powder, Vanilla Scent, 3 OZ (85 g) tube, Active Ingredient: Miconazole Nitrate 2.0% w/w Antifungal, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA, NDC: 53329-169-79

Product Quantity:

Reason for Recall:
CGMP deviations: the product was shipped from the Manufacturer to a Medline warehouse and released to stock while it was still under investigation for low assay results on the active ingredient miconazole nitrate.

Recall Number:
D-0091-2024

Code Information:
Lot 007782, Exp 08/31/2024

Class II Drugs Event

Event ID:
93260

Status:
Ongoing

Recall Initiation Date:
10/19/2023

Center Classification Date:
11/08/2023

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Oxybutynin Chloride Extended-Release Tablet USP, 5 mg, 100 count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-255-01

Product Quantity:

Reason for Recall:
Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.

Recall Number:
D-0096-2024

Code Information:
M212749, exp. date 11/2024; M214477, exp. date 11/2024; M214478, exp. date 11/2024; M214479, exp. date 11/2024; M214480, exp. date 11/2024

Product Description:
Oxybutynin Chloride Extended-Release Tablet USP, 10 mg, 100 count bottles Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-256-01.

Product Quantity:

Reason for Recall:
Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.

Recall Number:
D-0097-2024

Code Information:
M213318, exp. date 11/2024; M213314, exp. date 11/2024; M213315, exp. date 11/2024; M214436, exp. date 11/2024; M214437, exp. date 11/2024; M214438, exp. date 11/2024; M300653, exp. date 12/2024; M300654, exp. date 12/2024

Product Description:
Oxybutynin Chloride Extended-Release Tablet USP, 15 mg, 100 count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-257-01.

Product Quantity:

Reason for Recall:
Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.

Recall Number:
D-0098-2024

Code Information:
M211541, exp. date 10/2024 M211542, exp. date 10/2024 M212746, exp. date 10/2024 M300660, exp. date 12/2024

Class II Drugs Event

Event ID:
93263

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ranolazine Extended-Release Tablets 500mg, 60 Tablets per bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur Dist - Dhar, Madhya Pradesh - 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-319-60.

Product Quantity:
16,944 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification for dissolution.

Recall Number:
D-0092-2024

Code Information:
Lot # 17230388, Exp. 01/31/2025

Class III Drugs Event

Event ID:
93202

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AbbVie Inc.
1 N Waukegan Rd
North Chicago IL United States

Distribution Pattern:
Distributed in the US. No government or foreign consignees.

Associated Products

Product Description:
Synthroid, Levothyroxine Sodium Tablets, USP 125mcg (0.125mg), 100-count bottle, Rx Only AbbVie Inc. North Chicago, IL 60064, U.S.A. NDC 0074-7068-11

Product Quantity:
864 cartons

Reason for Recall:
Labeling: Wrong Barcode- One (1) of every forty (40) unit dose blister will contain incorrect barcode information that causes a 125mcg unit dose is scanned as 200mcg unit dose.

Recall Number:
D-0088-2024

Code Information:
Lot # 1187435 exp date: 02/2024

Class III Drugs Event

Event ID:
93254

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zyla Life Sciences US Inc.
100 Saunders Rd Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Oxaydo (oxycodone HCl, USP) tablets, 7.5 mg, 100 Tablets per bottle, Rx only, Distributed by: Zyla Life Sciences US Inc., Wayne, PA 19087. NDC: 69344-213-11

Product Quantity:
3,792 bottles

Reason for Recall:
Sub-potent Drug: Lower potency than labeled.

Recall Number:
D-0094-2024

Code Information:
Lot 22W02, Exp 01/31/2025

Class III Drugs Event

Event ID:
93322

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm LLC
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Nationwide and Saudi Arabia

Associated Products

Product Description:
Mycophenolate Mofetil for Oral Suspension, USP, 200 mg/mL, Rx Only, bottle, Manufactured for: VistaPharm, Inc., Largo, FL 33771, USA, NDC#66689-307-08.

Product Quantity:
11,633 bottles

Reason for Recall:
Defective Container: The adaptor does not fit into the neck of the bottle after reconstitution with water.

Recall Number:
D-0093-2024

Code Information:
Lot #: M23400A, M23401A, M23402A, Exp Date. 04/30/2025; M23591A, M23592A, Exp Date. 06/30/2025.

Class III Drugs Event

Event ID:
93337

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals Inc.
130 East Dr
Brampton Canada

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Hydrocortisone 1% and Acetic Acid 2% Otic Solution USP, 10ml dropper bottle, RX Only, Mfd. by: Taro Pharmaceuticals Inc. Brampton, Ontario, Canada LGT 1C, Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532. NDC 51672-3007-1

Product Quantity:
11,196 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:Out-of-Specification result for Hydrocortisone related impurity and slightly lower than the established level of the Hydrocortisone Assay obtained during stability testing.

Recall Number:
D-0089-2024

Code Information:
Lot# AC86809, AC86812, Exp Date: 01/31/2024

Class III Drugs Event

Event ID:
93354

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/09/2023

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Grato Holdings, Inc.
201 Apple Blvd
Woodbine IA United States

Distribution Pattern:
Distributed to one direct account in Florida with possible further distribution out of state.

Associated Products

Product Description:
V-FORCE Homeopathic, 1 FL OZ (30 ml) per glass bottle, Distributed by: BioActive Nutritional, Inc., 1803 N. Wickham Rd., Melbourne, FL 32935

Product Quantity:
1,333 30mL bottles

Reason for Recall:
Incorrect Product Formulation: product contains Active Ingredient Glandula Suprarenalis Suis 8X instead of Glandula Suprarenalis Bovine 8X (as stated on the product label).

Recall Number:
D-0099-2024

Code Information:
Lot: Z65842 no exp date on product