Enforcement Report - Week of April 10, 2024

Class II Drugs Event

Event ID:
94198

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/04/2024

Initial Firm Notification of Consignee or Public:
Letter

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:
Phenylephrine HCl, 1000 mcg/10 mL, 10 mL Total Volume per syringe, Intravenous, Rx Only, Hospital/Office Use Only, This is a Compounded Drug - Not for Resale, SSM Health Care Corporation Outsourcing Facility, 1015 Bowles Ave, Fenton, MO 63026-2394. NDC: 60652-0104-1

Product Quantity:
11,798 syringes

Reason for Recall:
Lack of Assurance of Sterility: Firm did not perform process validation.

Recall Number:
D-0435-2024

Code Information:
Lot #s: 20240109-837CB8, Exp. 07-Jul-2024; 20231219-08D09D, Exp. 16-Jun-2024; 20231121-20F8BB, Exp. 19-May-2024; 20231115-2FF64D, Exp. 13-May-2024; 20231101-09C52B, Exp. 29-Apr-2024; 20231010-3D0B35, Exp. 07-Apr-2024; 20230912-847E0C, Exp. 10-Mar-2024.

Product Description:
FentaNYL citrate, 10 mcg in 0.9% Sodium Chloride 1 mL Vial (10 mcg/mL), 1.5 mL Total Volume per Vial, Intravenous, Rx Only, Hospital/Office Use Only, SSM Health Care Corporation Outsourcing Facility, 1015 Bowles Ave, Fenton, MO 63026-2394. NDC: 60652-9010-1

Product Quantity:
140 vials

Reason for Recall:
Lack of Assurance of Sterility: Firm did not perform process validation.

Recall Number:
D-0436-2024

Code Information:
Lot: 20231031-0C91D9, Exo 29-Feb-2024.

Class II Drugs Event

Event ID:
94272

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/03/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 Mcgaw Ave
Irvine CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lactated Ringer's Injection USP, 1000mL, EXCEL CONTAINER, Rx only, B.Braun Medical Inc., Bethlehem, PA 18018, NDC 0264-7750-00

Product Quantity:
7,800 bags

Reason for Recall:
Lack of assurance of sterility: bags have the potential to leak..

Recall Number:
D-0431-2024

Code Information:
Lot #: J3N023, Exp: 31 March 2026

Class II Drugs Event

Event ID:
94275

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/03/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
IntegraDose Compounding Services LLC
719 Kasota Ave Se
Minneapolis MN United States

Distribution Pattern:
Nationwide within the U.S

Associated Products

Product Description:
fentaNYL Citrate 2,500 mcg/50mL in Sterile Water, 50 mL CADD for Injection, IntegraDose Compounding Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC 71139-6030-1

Product Quantity:
187 cassettes

Reason for Recall:
Lack of Assurance of Sterility: leaking bags

Recall Number:
D-0432-2024

Code Information:
Lot#: 20231020FEN-1, Exp: 04/17/2024

Class II Drugs Event

Event ID:
94280

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/02/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Twice-a-Day Dosage, 100 Capsules per bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ, 07430, Product of India, NDC 68462-562-01

Product Quantity:
6,528 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of Specification (OOS) was reported in test of dissolution at the 12th month time point in long term stability study.

Recall Number:
D-0430-2024

Code Information:
Lot #: 17230304, Exp. 12/31/2024.

Class III Drugs Event

Event ID:
94348

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/02/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
X-Gen Pharmaceuticals Inc.
300 Daniel Zenker Dr
Horseheads NY United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Cyclophosphamide for Injection, USP, 500mg/vial, Lyophilized, Cytotoxic Agent, Single Dose Vial for Intravenous Use, Rx Only, Manufactured for: XGen Pharmaceuticals DJB, Inc. Big Flats, NY 14814, NDC # 39822-0250-01.

Product Quantity:
1283 vials

Reason for Recall:
Labeling: Incorrect or missing Package Insert: There is an error on the Package Insert (PI), section 2.3, Preparation, Handling, and Administration. The concentration of the reconstituted product is listed as '20 mg per vial.' This information should read: '20 mg per mL'.

Recall Number:
D-0433-2024

Code Information:
Lot #: CIC1-23001 A, Exp. 08/30/2026

Product Description:
Cyclophosphamide for Injection, USP, 1g/vial, Lyophilized, Single Dose Vial, Discard unused solution, Cytotoxic Agent, After Reconstitution: For direct intravenous injection or must be further diluted before intravenous infusion, Rx Only, Manufactured for: XGen Pharmaceuticals DJB, Inc., Big Flats, NY 14814, NDC # 39822-0255-01.

Product Quantity:
1332 vials

Reason for Recall:
Labeling: Incorrect or missing Package Insert: There is an error on the Package Insert (PI), section 2.3, Preparation, Handling, and Administration. The concentration of the reconstituted product is listed as '20 mg per vial.' This information should read: '20 mg per mL'.

Recall Number:
D-0434-2024

Code Information:
Lot #: CIC2-23001 A, Exp. 11/30/2026