Enforcement Report - Week of September 11, 2024

Class I Drugs Event

Event ID:
95102

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/30/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
25212 W Il Route 120
Round Lake, IL 60073-9799
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Heparin (Heparin Sodium in 0.9% Sodium Chloride Injection), 2,000 units per 1,000 mL (2 units/mL), 1000 mL Sterile Single Dose Container, Rx Only, Baxter USA, NDC 0338-0433-04

Product Quantity:
44,208 containers

Reason for Recall:
Microbial Contamination of Sterile Products; out of limit results obtained for endotoxin testing.

Recall Number:
D-0649-2024

Code Information:
Lot # N008235, Exp 8/31/2024

Class II Drugs Event

Event ID:
95190

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/05/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ProRx LLC
619 Jeffers Cir
Exton, PA 19341-2540
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Semaglutide, 2 mL (2.5mg/mL), Compounded RX Product, Multidose SC inj, glass vial, ProRx, 267-565-7008, NDC 84139-225-01

Product Quantity:
2,490 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0650-2024

Code Information:
Lot #: ProRx031924, BUD 09/18/2024 ProRx032624, BUD 09/25/2024 ProRx041324, BUD 10/12/2024

Product Description:
Tirzepatide 2 mL (10 mg/mL) and 20 mg/mL, 2mL Multidose SC Injection vials, Compounded Rx Product, ProRx 267-565-7008, NDC 84139-210-01

Product Quantity:
37 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0651-2024

Code Information:
Lot # ProRx040924-1, BUD 10/08/2024

Product Description:
SEMAGLUTIDE 5mg/2mL (2.5mg/mL), Rx Only 2 mL Multiple Dose Vial, Rx Only, Compounded Drug, Mfd by: ProRX Exton, PA19341, NDC 84139-225-01

Product Quantity:
8,396 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0652-2024

Code Information:
Lot #: ProRx052424, BUD 11/23/2024 ProRx060724, BUD 12/06/2024 ProRx061124, BUD 12/10/2024 ProRx061924, BUD 12/18/2024

Product Description:
SEMAGLUTIDE 10mg/4mL (2.5mg/mL), 4 mL Multiple Dose Vial, Rx Only, Compounded Drug, Mfd by: ProRX Exton, PA19341, NDC 84139-225-04

Product Quantity:
1,960 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0653-2024

Code Information:
ProRx061424, BUD 12/13/2024

Product Description:
Semaglutide / Cyanocobalamin Injection: 2.5/0.5 mg/mL, 2 mL Multiple Dose Vial, Compounded Rx Product, ProRX 267-565-7008, NDC 84139-225-02

Product Quantity:
500 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0654-2024

Code Information:
Lot # ProRx031924-1, BUD 09/18/2024

Product Description:
TIRZEPATIDE 20 mg/2mL (10/mg/mL), Rx Only, 2mL Multiple Dose Vial, Mfd by: ProRx Exton, PA, 19341, NDC 84139-210-01

Product Quantity:
1,489 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0655-2024

Code Information:
Lot # ProRx051424, BUD 11/13/2024

Product Description:
TIRZEPATIDE 60 mg/3mL (20/mg/mL), Rx Only, 3mL Multiple Dose Vial, Mfd by: ProRx Exton, PA, 19341, NDC 84139-210-02

Product Quantity:
1,732 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0656-2024

Code Information:
Lot# ProRx052224, BUD 11/21/2024 ProRx061024, BUD 12/09/2024