Enforcement Report - Week of January 10, 2024

Class II Drugs Event

Event ID:
93690

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 920
Waltham MA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
DELFLEX Peritoneal Dialysis Solution in Biofine container 1.5% Dextrose, packaged in 6000mL bags, Rx only, Fresenius Medical Care NA Waltham, MA 02451, NDC 49230-206-62.

Product Quantity:
69,590 bags

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-0218-2024

Code Information:
Part Number: 077-60621, Lot #: 23JK02010, Exp. Date 1/31/2025

Class II Drugs Event

Event ID:
93708

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/04/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Seaway Pharma Inc.
5 County Route 42
Massena NY United States

Distribution Pattern:
MI, PA

Associated Products

Product Description:
Nasal Spray Original No Drip Oxymetazoline HCl Nasal Solution, 12 Hour Pump Mist, 1 FL oz. (30 mL) bottle, a) Quality Choice, Distributed by C.D.M.A. Inc., 43157 W 9 Mile Rd, Novi, MI 48375, NDC# 63868-607-01, UPC 6-35515-98843-9, b) Premier Value, Distributed by: Pharmacy Value Alliance, LLC, 407 East Lancaster Avenue, Wayne, PA 19087 UPC 8-40986-03509-8.

Product Quantity:
7,992 bottles

Reason for Recall:
CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.

Recall Number:
D-0214-2024

Code Information:
Lot # SD23032, Exp 04/30/2026

Product Description:
Premier Value Tussin Cough DM, Dextromethorphan HBr...Cough Suppressant, Guaifenesin...Expectorant, Alcohol Free, 8 FL OZ (237 mL) bottle, Distributed by: Pharmacy Value Alliance, LLC, 407 East Lancaster Avenue, Wayne PA 19087, UPC 8-40986-03789-4.

Product Quantity:
4,176 bottles

Reason for Recall:
CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.

Recall Number:
D-0215-2024

Code Information:
Lot # SD23033, Exp 04/30/2025

Product Description:
Quality Choice No Drip Extra Moisturizing Nasal Pump Mist Oxymetazoline hydrochloride 0.05%, 12 Hour Nasal Decongestant, 1 fl oz (30 mL) bottle, Distributed by C.D.M.A, Inc. 43157 W 9 Mile Rd. Novi, MI 48375, NDC# 63868-676-01, UPC 6-35515-98847-7.

Product Quantity:
7,992 bottles

Reason for Recall:
CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.

Recall Number:
D-0216-2024

Code Information:
Lot # SE23034, Exp 05/31/2026

Product Description:
Quality Choice No Drip Severe Congestion Nasal Pump Mist, Oxymetazoline hydrochloride 0.05%, Nasal Decongestant, 12 Hours, 1 fl. oz. bottle, Distributed by C.D.M.A., Inc., 43157 W 9 Mile Rd., Novi, MI 48375, NDC 63868-608-01, UPC 6-35515-98846-0

Product Quantity:
8,160 bottles

Reason for Recall:
CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.

Recall Number:
D-0217-2024

Code Information:
Lot # SE23035, Exp 05/31/2026

Class III Drugs Event

Event ID:
93552

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Azurity Pharmaceuticals, Inc.
841 Woburn St
Wilmington MA United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Eprontia (topiramate) oral solution, 25 mg/mL, 473 mL Bottle, Rx only, Manufactured for: Azurity Pharmaceuticals, Woburn, MA 01801, NDC 52652-9001-1

Product Quantity:
2,220 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification Impurity C (4,5-desisopropylidene topiramate) result observed during routine stability testing at 18 months.

Recall Number:
D-0213-2024

Code Information:
Lot #: MB22020B, Exp 12/27/2023