Enforcement Report - Week of August 13, 2025

Class II Drugs Event

Event ID:
97251

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/04/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville, GA 30534-6828
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Duloxetine D/R, 20 mg, 30 Caps, 30-count bottle, RX Only, Packaged & Distributed by: Direct Rx, Dist. By Breckenridge Pharm., Inc., Berlin, CT 06037, NDC 61919-422-30

Product Quantity:
16 bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit.

Recall Number:
D-0567-2025

Code Information:
Lot #: 02AU2406, Exp 01/31/2027

Product Description:
Duloxetine D/R, 30 mg, 30 Caps, RX Only, Packaged as a) 30-count bottle NDC 61919-0482-30, b) 60-count bottle, NDC 61919-0482-60, c) 90-count bottle, NDC 61919-0482-90; Packaged & Distributed by: Direct Rx, Dist. By Breckenridge Pharm., Inc., Berlin, CT 06037,

Product Quantity:
875 bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit.

Recall Number:
D-0568-2025

Code Information:
Lot #: a) 15AU2420, 01JY2407, 04OC2411, Exp 01/31/2027; 12SE2418, 24OC2424, 20NO2416, Exp 03/31/2027; 21AU2313, 21JY2311, 05JY2313, Exp Date 01/31/2026 b) 13OC2310, 05SE2304, 04AU2306, 21JY2317, 12JY2306, Exp 01/31/2026; 11JY2416, 28JU2414, 19AU2412, 02AU2409, Exp 01/31/2027; 11SE2416, 24OC2425, Exp 03/31/2027; c) 23AU2317, 21AU2314, Exp 01/31/2026.

Class II Drugs Event

Event ID:
97276

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/01/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc.
200 Connell Dr Ste 4200
Berkeley Heights, NJ 07922-2805
United States

Distribution Pattern:
U.S Nationwide

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60mg, 1,000-count bottles, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Distributed by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-748-10.

Product Quantity:
1,829 60-count bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above safety assessment limit

Recall Number:
D-0552-2025

Code Information:
Lot: 230836C, Exp.: 02/28/2026

Class II Drugs Event

Event ID:
97292

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/01/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
AEQUITA PHARMACY
12825 Ne 126th Pl
Kirkland, WA 98034-7721
United States

Distribution Pattern:
MA

Associated Products

Product Description:
Semaglutide + Cyanocobalamin 0.22 mg + 0.25mg/0.5 ml Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
290 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0553-2025

Code Information:
All Lots within expiry

Product Description:
Tirzepatide + Niacinamide 2.2 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
236 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0554-2025

Code Information:
All Lots within expiry

Product Description:
Tirzepatide + Niacinamide 4.4 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
170 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0555-2025

Code Information:
All Lots within expiry.

Product Description:
Tirzepatide + Niacinamide 6.6 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
160 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0556-2025

Code Information:
All Lots within expiry.

Product Description:
Tirzepatide + Niacinamide 8.8 mg + 1.0mg/0.5 ml Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
139 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0557-2025

Code Information:
All Lots within expiry.

Product Description:
Tirzepatide + Niacinamide 11.24 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
146 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0558-2025

Code Information:
All Lots within expiry.

Product Description:
Tirzepatide + Niacinamide 13.2 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
143 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0559-2025

Code Information:
All Lots within expiry.

Product Description:
Tirzepatide + Niacinamide 16.6 mg + 1.0mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 3 x 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
155 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0560-2025

Code Information:
All Lots within expiry.

Product Description:
Semaglutide + Cyanocobalamin 0.44 mg + 0.25mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
221 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0561-2025

Code Information:
All Lots within expiry.

Product Description:
Semaglutide + Cyanocobalamin 0.88 mg + 0.25mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
194 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0562-2025

Code Information:
All Lots within expiry.

Product Description:
Semaglutide +Cyanocobalamin 1.5 mg + 0.25mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
190 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0563-2025

Code Information:
All Lots within expiry.

Product Description:
Semaglutide + Cyanocobalamin injection solution, 2.21 mg + 0.25mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
176 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0564-2025

Code Information:
All Lots within expiry.

Product Description:
Semaglutide + Cyanocobalamin 2.67 mg + 0.25mg/0.5 mL Inj Sol, Inject 0.5 mL (50 units on syringe) subcutaneously, Sterile, 2 mL Multi Dose Vial, Refrigerate, Do not freeze, Aequita Pharmacy LLC, Kirkland, WA 98034.

Product Quantity:
158 vials

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0565-2025

Code Information:
All Lots within expiry.

Class II Drugs Event

Event ID:
97323

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/25/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/01/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Alembic Pharmaceuticals Limited
Formulation Division, Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol
Panchmahal
India

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Doxepin Hydrochloride Capsules, USP, 10 mg, 100 Capsules, Rx only, Manufactured by: Alembic Pharmaceuticals Limited, Panela v 389350, Gujarat, India, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, NDC 62332-637-31

Product Quantity:
9,492 bottles

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit.

Recall Number:
D-0566-2025

Code Information:
Lot: 2305015142, Exp. Date: 9/30/2025

Class II Drugs Event

Event ID:
97360

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/30/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/07/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cardinal Health Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091
United States

Distribution Pattern:
Nationwide Within the U.S.

Associated Products

Product Description:
Xolair (omalizumab injection), 150 mg/ml, 1 auto-injector, Rx only, Genentech, Inc, South San Francisco, CA 9408, NDC: 50242-215-55.

Product Quantity:
6 units

Reason for Recall:
CGMP Deviations - Product was exposed to temperatures outside the product's labeled storage requirements.

Recall Number:
D-0571-2025

Code Information:
Lot: 3617756, Expires: 12/31/2025.

Product Description:

Xolair (omalizumab injection), 75 mg/0.5 ml, Rx only, Genentech, Inc., South San Francisco, CA 94080, NDC 50242-214-55

Product Quantity:
4 units

Reason for Recall:
CGMP Deviations - Product was exposed to temperatures outside the product's labeled storage requirements.

Recall Number:
D-0572-2025

Code Information:
Lot: 3630004, Expires: 10/31/2025.

Product Description:
RECOMBINATE, [Antihemophilic Factor (Recombinant)], 5 mL vials, Rx Only, Takeda Pharmaceuticals USA, Cambridge, MA 02142, NDC: 00944-2843-01

Product Quantity:
3 units

Reason for Recall:
CGMP Deviations - Product was exposed to temperatures outside the product's labeled storage requirements.

Recall Number:
D-0573-2025

Code Information:
Lot: TRB23802AC, Expires: 03/18/2026; TRA22804AA, Expires: 10/18/2025

Class II Drugs Event

Event ID:
97391

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/07/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Spironolactone Tablets, USP, 25 mg, 100-count bottle, Rx only, Mfg. by: Frontida BioPharm, Inc., 1100 Orthodox St, Philadelphia, PA 19124, Dist. by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 53489-143-01

Product Quantity:
11,328 bottles

Reason for Recall:
Presence of foreign substance: identified as aluminum.

Recall Number:
D-0574-2025

Code Information:
Lot # P3314, Exp 11/30/2026