Enforcement Report - Week of May 7, 2025

Class II Drugs Event

Event ID:
96637

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
NC, SC, VA

Associated Products

Product Description:
Wegovy (semaglutide) injection, 2.4 mg/0.75 mL, 4 Single-Dose Prefilled Pens per Carton, For Subcutaneous Use Only, Rx Only, Single-Dose Only, Novo Nordisk Inc., Plainsboro, NJ 08536, Manufactured by: Novo Nordisk A/S, DK-2880, Bagsvaerd, Denmark, NDC 0169-4524-14.

Product Quantity:
48 Cartons

Reason for Recall:
Temperature abuse: Wegovy product was potentially exposed to temperatures outside of the products labeled storage conditions due to a shipping error involving a Cardinal Health distribution center. More specifically, product was removed from refrigerated storage for an extended period of time and inappropriately released.

Recall Number:
D-0393-2025

Code Information:
Lot PZFDE06, Exp 08/31/2025

Class II Drugs Event

Event ID:
96666

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/30/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ACCORD HEALTHCARE, INC.
8041 Arco Corporate Dr Ste 200
Raleigh, NC 27617-2010
United States

Distribution Pattern:
Nationwide US.

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP, 25 mcg (0.025 mg), 1000 bottles, Rx Only, Manufactured for Accord Healthcare, Inc., Raleigh, NC 27617, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-447-17

Product Quantity:
4,888 Bottles

Reason for Recall:
Subpotent

Recall Number:
D-0394-2025

Code Information:
Lot # D2300323, Exp Date: 01/2026

Product Description:
Levothyroxine Sodium Tablets, USP, 50 mcg (0.05 mg), 1000 bottles, Rx Only, Manufactured for Accord Healthcare, Inc., Raleigh, NC 27617, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-448-17.

Product Quantity:
4,872 Bottles

Reason for Recall:
Subpotent

Recall Number:
D-0395-2025

Code Information:
Lot # D2400547, Exp Date: 02/2026

Product Description:
Levothyroxine Sodium Tablets, USP, 88 mcg (0.088 mg), 1000 bottles, Rx Only, Manufactured for Accord Healthcare, Inc., Raleigh, NC 27617, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-450-17

Product Quantity:
4,885 Bottles

Reason for Recall:
Subpotent

Recall Number:
D-0396-2025

Code Information:
Lot # D2300044, Exp Date: 12/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 112 mcg (0.112 mg), 90 bottles, Rx Only, Manufactured for Accord Healthcare, Inc., Raleigh, NC 27617, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-452-15

Product Quantity:
18,984 Bottles

Reason for Recall:
Subpotent

Recall Number:
D-0397-2025

Code Information:
Lot # D2400725, Exp Date: 03/2026

Class II Drugs Event

Event ID:
96695

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/01/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Regent, Inc.
6610 New Albany Rd E
New Albany, OH 43054-8730
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
niCARdipine Hydrochloride Injection, USP, 25 mg/10 mL (2.5 mg/mL), 10 mL Single Dose Vial, Rx Only, Mfd for: Civica, Inc., Lehi, UT 84043,Mfd by: American Regent, Inc., New Albany, OH 43064. NDC Carton: 72572-470-10/ NDC Vial: 72572-470-01.

Product Quantity:
29,777 (cartons of 10 x 10mL vials)

Reason for Recall:
Lack of sterility assurance: Product leakage around the vial neck, which could potentially result in a lack of sterility assurance.

Recall Number:
D-0398-2025

Code Information:
Lots, expiry: Lot 24025N0C0, 6/30/2025; Lot 24115N0C0, 10/31/2025; Lot 24116N0C0, 3/31/2026; Lot 24160N0C0, 12/31/2025; Lot 24217N0C0, 01/31/2026; Lot 24288N0C0, 04/30/2026; Lot 24331N0C0, 5/31/2026

Product Description:
niCARdipine Hydrochloride Injection, USP, 25 mg/10 mL (2.5 mg/mL), 10 mL Single Dose Vial, Rx Only, American Regent, Inc., Shirley, NY 11967. NDC carton: 0517-0735-10 / NDC Vial: 0517-0735-01]

Product Quantity:
7,249 (cartons of 10 x 10 mL vials)

Reason for Recall:
Lack of sterility assurance: Product leakage around the vial neck, which could potentially result in a lack of sterility assurance.

Recall Number:
D-0399-2025

Code Information:
Lots, expiry: Lot 24086N0C0, 7/31/2025; Lot 24076N0C0, Lot 24090N0C0, 8/31/2025, Lot 25011N0C0, 6/30/2026;

Class II Drugs Event

Event ID:
96699

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nubratori, Inc
381 Van Ness Ave Ste 1507
Torrance, CA 90501-7220
United States

Distribution Pattern:
PA and CA.

Associated Products

Product Description:
Dexonto 0.4% (dexamethasone sodium phosphate) solution 20 mg/5 mL (4 mg/mL), Rx Only, 12 - 5 mL Single Dose Units per box, Preservative Free, For Iontophoresis Use Only, Non-Sterile Product, Not for Injection, NUBRATORI RX, 381 Van Ness Ave# 1507, CA 90501, NDC 71300-6564-1 (box), 71300-6564-3 (vial).

Product Quantity:
20 boxes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Expiration date: Individual vials of Dexonto 0.4%, are labeled correctly with the BUD of 12/25/2024, however, the outer box on some of the Dexonto 0.4% are labeled incorrectly with a BUD of 12/25/2025.

Recall Number:
D-0392-2025

Code Information:
Lot #: C04292401X1, BUD: 12/25/2025 (box).

Class II Drugs Event

Event ID:
96718

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/25/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Tirofiban Hydrochloride Injection 5 mg/100 mL (50 mcg/mL), 100 mL single-dose container (bag), Rx only, Manufactured in India for: Eugia U.S. LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520, NDC 55150-429-01

Product Quantity:
18,867 bags

Reason for Recall:
Out-of-Specification test results were obtained in at long term conditions during 3 month's stability study for related substances.

Recall Number:

D-0389-2025

Code Information:
Lot #: 3TF24002A, Exp 11/30/2026

Product Description:
Tirofiban Hydrochloride Injection 12.5 mg/250 mL (50 mcg/mL), 250 mL single-dose container (bag), Rx only, Manufactured in India for: Eugia U.S. LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520, NDC 55150-430-01

Product Quantity:
N/A

Reason for Recall:
Out-of-Specification test results were obtained in at long term conditions during 3 month's stability study for related substances.

Recall Number:
D-0390-2025

Code Information:
Lot# : 3TF24001, Exp 3/31/2026

Class II Drugs Event

Event ID:
96744

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/25/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/01/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Mckesson Medical-Surgical Inc. Corporate Office
9954 Maryland Drive Deep Run Iii Ste. 4000
Richmond, VA 23233
United States

Distribution Pattern:
Distributed to Medical Facilities in MS and FL.

Associated Products

Product Description:
Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg / mL, 1 mL Single-Dose Vial, Rx only, Mfd. in India for: Eugia US LLC, E. Windsor, NJ 08520, NDC 55150-0330-01

Product Quantity:
3

Reason for Recall:
Severe thunderstorms caused transit delays of certain cold chain products that were shipped on 02-Apr-2025 and delivered after the 48-hours specified delivery time, on 07-Apr-2025 and 08-Apr-2025. The affected products may not have been stored at the recommended labeled storage conditions which may have impacted the safety, quality, identity, potency and purity of the product.

Recall Number:
D-0400-2025

Code Information:
Lot #: 1MP24042, Exp 6/30/26

Product Description:
Infuvite Adult, multiple vitamins injection, Baxter, Five of Vial 1 (5 mL) and Five of Vial 2 (5mL), Rx Only, Sterile, Manufactured for: Sandoz Inc., Princeton, NJ 08540, Distributed by Baxter Healthcare Corporation, Deerfield, IL 60015 USA, Product of Canada, NDC 54643-5649-1

Product Quantity:

15

Reason for Recall:
Severe thunderstorms caused transit delays of certain cold chain products that were shipped on 02-Apr-2025 and delivered after the 48-hours specified delivery time, on 07-Apr-2025 and 08-Apr-2025. The affected products may not have been stored at the recommended labeled storage conditions which may have impacted the safety, quality, identity, potency and purity of the product.

Recall Number:
D-0401-2025

Code Information:
Lot #: AA2279, Exp 8/31/26; AA2383, Exp 9/30/26

Class II Drugs Event

Event ID:
96756

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim, CA 92807-1801
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Clindamycin Hydrochloride Capsules, USP, 300mg, 30-count bottles, Manufactured by: Glenmark Pharmaceuticals Limited, NDC 68788-8685-03.

Product Quantity:
1190 Bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0391-2025

Code Information:
Lot #: L0224T, K1824M, K0124N, J1624V, J0824O, I2424E, I1024O, A0925F, L2324L, Exp: 7/31/2026.