Enforcement Report - Week of January 15, 2025

Class I Drugs Event

Event ID:
95778

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Endo USA, Inc.
1400 Atwater Dr
Malvern, PA 19355-8701
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Clonazepam Orally Disintegrating Tablet, USP, 2 mg, C-IV, Rx Only, 60 Tablets per carton, 10 blister cards containing 6 tablets each, Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-310-02 (carton), NDC#: 49884-310-52 (blisters).

Product Quantity:
9,816 cartons

Reason for Recall:
Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.

Recall Number:
D-0178-2025

Code Information:
Lot # 550176501, 550176601, Exp 02/28/2027.

Product Description:
Clonazepam Orally Disintegrating Tablets, USP, 0.125 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-306-02 (carton), NDC #: 49884-306-52 (blisters).

Product Quantity:
8,029 cartons

Reason for Recall:
Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.

Recall Number:
D-0179-2025

Code Information:
Lot #: 550174101, Exp. 01/31/2027.

Product Description:
Clonazepam Orally Disintegrating Tablets, USP, 0.25 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-307-02 (carton), NDC #: 49884-307-52 (blisters).

Product Quantity:
72,973 cartons

Reason for Recall:
Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.

Recall Number:
D-0180-2025

Code Information:
Lot #s: 550142801, 550142901, 550143001, 550143101, 550143201, 550143301, 550143401, 550147201, 550147401, Exp. 08/31/2026.

Product Description:
Clonazepam Orally Disintegrating Tablets, USP, 1 mg, C-IV, Rx Only, 60 tablets per carton (10 blister cards containing 6 tablets each), Distributed by: PAR Pharmaceutical, Chestnut Ridge, NY 10977, NDC#: 49884-309-02 (carton), NDC #: 49884-309-52 (blisters).

Product Quantity:
22,513 cartons

Reason for Recall:
Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled. The blister strips inside the product carton reflect the correct strength.

Recall Number:
D-0181-2025

Code Information:
Lot #s: 550145201, Exp. 08/31/2026; 550175901, 550176001, 550176201, Exp. 02/28/2027

Class I Drugs Event

Event ID:
95980

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Buy-Herbal
13661 41st Ave Box 239
Flushing, NY 11355-2464
United States

Distribution Pattern:
U.S Nationwide.

Associated Products

Product Description:
Nhan Sam Tuyet Lien Truy Phong Hoan, Capsules, 30-Count Bottles, Manufactured by Yee Hong Pharmaceuticals, SDN, Penang, Malasia.

Product Quantity:
26 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found the products to be tainted with undeclared Furosemide, Dexamethasone and Chlorpheniramine

Recall Number:
D-0177-2025

Code Information:
All codes, unknown expiration dates all before 05/2030.

Class II Drugs Event

Event ID:
95836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Draximage Inc., dba Jubilant Radiopharma
16751 Rte Transcanadienne
Kirkland
Canada

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection, 10 mL Multi-Dose Reaction Vial, 5 vial Box, Rx Only, Manufactured for: Jubilant Draximage Inc., dba Jubilant Radiopharma, Kirkland , Quebec, H9H, 4J$, Canada, NDC# 65174-179-05.

Product Quantity:
5209 kits

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0191-2025

Code Information:
LOT C2300070 and C2300070E;Exp. May 31, 2025

Class II Drugs Event

Event ID:
96014

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/16/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ciprofloxacin Ophthalmic Solution USP, 0.3% as base, Sterile, package in 5 mL bottles, Rx Only, Distributed by: Leading Pharma LLC, Fairfield, NJ. Manufactured by: FDC Limited, Maharashtra, India, NDC 69315-308-05

Product Quantity:
136,181 bottles

Reason for Recall:
Defective container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle

Recall Number:
D-0182-2025

Code Information:
Lot: 083L111, Exp. 11/30/2025; 084A032, Exp. 12/31/2025

Class II Drugs Event

Event ID:
96017

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/13/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/06/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Clobazam Tablets, 10 mg, packaged in 30 tablets per carton (3x10 blister cards each), Rx Only, Amneal Pharmaceuticals LLC, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 60687-423-21

Product Quantity:
5,178 cartons

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0184-2025

Code Information:
Lot #: 1019594, Exp. Date 12/31/2025

Class II Drugs Event

Event ID:
96018

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/06/2025

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:
Nationwide in the US

Associated Products

Product Description:
medroxyPROGESTERone Acetate Injectable Suspension, USP, 150mg per mL, Rx only, 1 mL Single-Dose Vial, Mfd in India for: Eugia US LLC, NJ 08520 NDC 55150-329-01 Shipper label: medroxyPROGESTERone Acetate Injectable Suspension, USP, 150 mg per mL, Distributed by: Eugia US LLC, NJ, Manufactured by: Eugia Pharma Specialties Limited, India

Product Quantity:
19872 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0185-2025

Code Information:
Lot No.: 1MP24069, Exp.: 08/2026

Class II Drugs Event

Event ID:
96026

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Granules Pharmaceuticals Inc.
3701 Concorde Pkwy
Chantilly, VA 20151-1126
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Colchicine Capsules 0.6 mg, 30-count bottles, Rx only, Manufactured by: Granules Pharmaceuticals Inc. Chantilly, VA 20151 NDC 70010-001-03

Product Quantity:
96 Bottles

Reason for Recall:
Out of specification observed during the accelerated stability conditions for the 30 count bottles.

Recall Number:
D-0187-2025

Code Information:
Lot#: GPC240763B, Exp. Date 6/17/2026

Class II Drugs Event

Event ID:
96073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/27/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2025

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:
Distributed Nationwide in the USA.

Associated Products

Product Description:
Progesterone Injection USP, 500mg per 10 mL (50mg/mL), 10 mL Multiple Dose Vial, Rx Only, Mfd. in India for: Eugia US LLC. E. Windsor NJ 08520 NDC # 55150-306-10

Product Quantity:
17,300 10-mL vials

Reason for Recall:
Presence of Particulate Matter: A market complaint was received of a glass piece in the vial.

Recall Number:
D-0186-2025

Code Information:
Batch # 1PR24010, Expiry: 02/28/2027

Class II Drugs Event

Event ID:
96074

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharma Holding, Inc.
2 Tower Center Blvd Ste 1401
East Brunswick, NJ 08816-1149
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP 30 mg, a) 30 count (NDC 57237-018-30) and b) 1000 count (NDC 57237-018-99) bottles, Rx only, Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ

Product Quantity:
42,527 bottles

Reason for Recall:
CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.

Recall Number:
D-0188-2025

Code Information:
a) Lot# DT3023051A, exp. date Apr-25; b) DT3023025A, exp. date Jan-25

Product Description:
Duloxetine Delayed-Release Capsules USP 20 mg, 60 count bottles, Rx only, Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ NDC 57237-017-60

Product Quantity:
73,680 bottles

Reason for Recall:
CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.

Recall Number:
D-0189-2025

Code Information:
Lot # DT2023003A, DT2023007A, DT2023008A, exp. date Jan-25

Product Description:
Duloxetine DR Capsules USP 60 mg, a) 30 count (NDC 57237-019-30) and b) 1000 count (NDC 57237-019-99) bottles; Distributed by: Rising Pharm Holdings, Inc., East Brunswick, NJ

Product Quantity:
244,460 bottles

Reason for Recall:
CGMP Deviations; Presence of N-nitroso-duloxetine impurity above recommended interim limit.

Recall Number:
D-0190-2025

Code Information:
Lot # a) DT6023053A, DT6023061A, DT6023068A, DT6023074A, exp. date Jan-25; DT6023078A, DT6023076A, exp. date Feb-25; DTC24043A, DTC24044A, exp. date Dec-25 b) DT6023002A, DT6023016A, DT6023036A, exp. date Dec-24; DT6023048A, exp. date Jan-25

Class II Drugs Event

Event ID:
96082

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/08/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Granules Pharmaceuticals Inc.
3701 Concorde Pkwy

Chantilly, VA 20151-1126
United States

Distribution Pattern:
Distributor in OH.

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, 1000-count bottles, Rx Only, Manufactured by: Granules India Limited, Hyderabad- 500 081, India, Manufactured for: Quallent Pharmaceuticals Health LLC, Grand Cayman, Grand Cayman Islands, NDC 82009-117-10

Product Quantity:
6,804 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: A Paracetamol 500 mg tablet was found in a 1000-count bottle of Metformin HCL ER Tablets USP, 500 mg.

Recall Number:
D-0192-2025

Code Information:
Lot #: 4911311A, Exp. Date: 11/2025

Class III Drugs Event

Event ID:
95999

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus, OH 43228-9579
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Methadone Hydrochloride Tablets, USP, 5mg, 10x10 Unit-Dose Tablets, Rx Only, Distributed by: Hikma Pharmaceuticals USA Inc., Berkeley Heights, NJ 07922, NDC 0054-0709-20

Product Quantity:
2591 100-count boxes

Reason for Recall:
Failed Tablet/Capsule Specifications: Illegible product identification for the unit dose configuration only.

Recall Number:
D-0183-2025

Code Information:
Lot # AC2556A; Exp. 03/2027