

Enforcement Report - Week of August 7, 2024

Class I Drugs Event

Event ID:

94945

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/10/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/30/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Endo Pharmaceuticals, Inc.

1400 Atwater Dr

Malvern, PA 19355-8701

United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico

Associated Products

Product Description:

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

Product Quantity:

8,139 cartons

Reason for Recall:

Labeling: Label Error on Declared Strength; Some cartons were incorrectly labeled as 0.125 mg instead of 0.25 mg. The blister strips inside the product carton reflect the correct strength of 0.25 mg.

Recall Number:

D-0622-2024

Code Information:

Lot 550147301, Exp. 08/31/2026

Class I Drugs Event

Event ID:

94946

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

06/25/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/28/2024

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Amerisource Health Services LLC

2550 John Glenn Ave Ste A

Columbus, OH 43217-1188

United States

Distribution Pattern:

US Nationwide.

Associated Products

Product Description:

Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, a), 100-count bottle (NDC 68001-396-00), b) 500-count bottle (NDC 68001-396-03), Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Distributed by: Dhar, Madhya Pradesh 454 775, India, Distributed for: BluePoint Laboratories.

Product Quantity:

61,231 bottles

Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0619-2024

Code Information:

[100 count bottles]: Lot 17221738, Exp 07/31/2024; Lot 17222494, Exp 10/31/2024; Lot 17230533, Exp 01/31/2025; Lot 17232208, Exp 09/30/2025; [500 count bottles]: Lot 17221823, Lot 17221830, Exp 07/31/2024; Lot 17221831, Exp 08/31/2024; Lot 17230248, Lot 17230253, Lot 17230271, Exp 12/31/2024; Lot 17230796, Lot 17230820, Exp 02/28/2025; Lot 17230825, Lot 17230833, Lot 17230840, Exp 03/31/2025; Lot 17231537, Lot 17231540, Lot 17231719, Lot 17231737, Exp 06/30/2025; Lot 17232111, Lot 17232164, Exp 09/30/2025

Class I Drugs Event

Event ID:

94978

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/12/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/29/2024

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

SoloVital
2571 Mast Way #203
Chula Vista, CA 91914-4539
United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Umary Acido Hialuronico, Suplemento Alimenticio, 850 mg caplets, packaged in 30-count bottles.

Product Quantity:

1,331 bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared Diclofenac and Omeprazole.

Recall Number:

D-0620-2024

Code Information:

All lots within Expiry

Class II Drugs Event

Event ID:

95022

Product Type:

Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Glenmark, Azelaic Acid Gel, 15 %, 50 grams, Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Colvale-Bardez, Goa, 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-626-52.

Product Quantity:
14,004 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0621-2024

Code Information:
Lot# 19241453; Exp MARCH 2026

Class II Drugs Event

Event ID:
95027

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/01/2024

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:
U.S. A. Nationwide

Associated Products

Product Description:
Ciprofloxacin ophthalmic solution USP, 0.3% as base, package in bottles: a) 10 mL (NDC 69315-308-10), b) 2.5 mL (NDC 69315-308-02), Rx Only, Distributed by: Leading Pharma LLC, Fairfield, NJ. Manufactured by: FDC Limited, Maharashtra, India.

Product Quantity:
66,528 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-0623-2024

Code Information:

Lot#: a) 084C040, Exp 02/28/2026; b) 084A024, Exp12/31/2025.

Class II Drugs Event

Event ID:

95059

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

07/26/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/01/2024

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

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

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Progesterone Injection, USP, 500 mg 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:

17136 vials

Reason for Recall:

Presence of Particulate Matter: Complaint received of a glass particle in the vial.

Recall Number:

D-0624-2024

Code Information:

Lot #: CPR230029A