Enforcement Report - Week of January 1, 2025

Class II Drugs Event

Event ID:
95777

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/26/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
MXBBB
1162 Tio Dink Cir
El Paso, TX 79907-1912
United States

Distribution Pattern:
Product was sold via Amazon Marketplace.

Associated Products

Product Description:
UMARY ACID HYALURONIC, 850 MG CAPLETS, 30-count bottle, UPC7502265120323

Product Quantity:
321 bottles

Reason for Recall:
cGMP Deviations: the firm initiated a recall after notification from the distributor that product may be tainted with undeclared diclofenac and omeprazole, however there is no analytical data confirming that product distributed by the firm is tainted.

Recall Number:
D-0166-2025

Code Information:
Lot#: 24183, Exp 07/01/28

Class II Drugs Event

Event ID:
95839

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/26/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Curium US, LLC
2703 Wagner Pl
Maryland Heights, MO 63043-3421
United States

Distribution Pattern:
Nationwide USA and Canada.

Associated Products

Product Description:
Kit for the Preparation of Technetium Tc 99m Sestamibi Injection, Each Kit contains: 30 sterile and non-pyrogenic reaction vials each containing Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetratluoroborate - 1 mg; Stannous Chloride Dihydrate - 0.D75 mg; L-Cysteine Hydrochloride Monohydrate - 1 mg; Sodium Citrate Dihydrate - 2.6 mg; Mannitol - 20 mg. The pH is adjusted to 5.6 to 5.7 with HCl or NaOH prior to lyophilization. Sealed under nitrogen. 30 Radioassay Information Labels with radiation warning symbol. 1 package insert, Rx only, Manufacture by: Curium US LLC, Maryland Heights, MO 63043, 69945-092-40

Product Quantity:
5,160 vials (172 kits 30 vials/kit)

Reason for Recall:
Lack of Assurance of Sterility; Improper crimps on vials impacting the integrity of the product

Recall Number:
D-0164-2025

Code Information:
Lot 092-24006, Catalog # N092D0, Exp 06/15/2026

Class II Drugs Event

Event ID:
95853

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin, CT 06037-2352
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, 90-count bottles (NDC 51991-747-90) Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.

Product Quantity:
163,883 bottles

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

Recall Number:
D-0161-2025

Code Information:
Lot # 222205C, exp. date 11/2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx Only, 90-count bottles (NDC 51991-748-90) Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.

Product Quantity:

76,968 bottles

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

Recall Number:
D-0162-2025

Code Information:
Lot # 230077C, exp. date 11/2025

Class II Drugs Event

Event ID:
95900

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/02/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/26/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana, PA 15701-3571
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, 60 mg, a) 30 count blister cards (NDC 70518-0937-04), b) 30 count bottles (NDC 70518-0937-03), Rx only, Source NDC 57237-0019-99, MFG: Rising Pharma, Inc., Allendale, NJ, Repackaged by: RemedyRepack Inc., Indiana, PA

Product Quantity:
a) 1,564 cards, b) 799 bottles

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

Recall Number:
D-0165-2025

Code Information:
a) NDC 70518-0937-04, Lot # J0786744-061724, Exp. 06/30/2025 b) NDC 70518-0937-03, Lot # B3002625-060524, Exp. 10/31/2025

Class II Drugs Event

Event ID:
95922

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.

727 N Ann Arbor Ave
Oklahoma City, OK 73127-5822
United States

Distribution Pattern:
Distributed within US: FL, MS, WI

Associated Products

Product Description:
DULoxetine DR USP, 30 mg, 90-count bottle, Rx Only, Packaged by: PD Rx Pharmaceuticals Inc, Oklahoma City, OK 73127, NDC: 43063-877-90

Product Quantity:
70, 90-count bottles

Reason for Recall:
CGMP Deviations: the presence of a Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit

Recall Number:
D-0163-2025

Code Information:
Lot # I24E77, A24E49, Exp Date: 04/30/25; J23C50, J23C97, L23B39, L23E98, Exp Date: 01/31/2025

Class II Drugs Event

Event ID:
95936

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/11/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2024

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:
USA Nationwide

Associated Products

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 10mg, 100-count bottle, RX only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ; Product of India, NDC 68462-861-01

Product Quantity:
3,888

Reason for Recall:
CGMP Deviations: N-Nitroso-Desmethyl Chlorpromazine impurity (NNDCI) were found to be failing per current FDA recommended limit.

Recall Number:
D-0159-2025

Code Information:
Lot#: 17230132, Exp 12/2024; 17230449, Exp 01/2025

Product Description:
chlorproMAZINE Hydrochloride Tablets, USP, 25 mg, 100-count bottle, RX only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ; Product of

India, NDC 68462-862-01

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations: N-Nitroso-Desmethyl Chlorpromazine impurity (NNDCI) were found to be failing per current FDA recommended limit.

Recall Number:
D-0160-2025

Code Information:
Lot#: 17230133, Exp 12/31/2024

Class II Drugs Event

Event ID:
95953

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/23/2024

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 in the USA

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 30 mg, Rx only, 30 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-414-04

Product Quantity:
21,262 bottles

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

Recall Number:
D-0155-2025

Code Information:
Lot DT3023029A Exp 02/28/2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30 mg, Rx only, 90 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-414-05

Product Quantity:
13,678 bottles

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

Recall Number:
D-0156-2025

Code Information:
Lot DT3023030A Exp 2/28/2025

Product Description:
Duloxetine Delayed-Release Capsules USP, 60 mg, Rx only, 30 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-04

Product Quantity:
20,734 30-count bottles

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

Recall Number:
D-0157-2025

Code Information:
Lot DT6023061B Exp 01/31/2025

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx only, 1,000 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-08

Product Quantity:
1,815 bottles

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

Recall Number:
D-0158-2025

Code Information:
Lots, expiry: Lot DT6022166A, exp 11/30/2024; Lot DT6023071A, exp 2/28/2025