Enforcement Report - Week of August 20, 2025

Class II Drugs Event

Event ID:
97254

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/13/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Merck & Co. Inc
126 E Lincoln Ave
Rahway, NJ 07065-4607
United States

Distribution Pattern:
Nationwide in the USA and PR.

Associated Products

Product Description:
Belsomra (suvorexant) tablets, 10mg, 30 Tablets in 3 Blister Cards per Carton, Each Blister Card contains 10 Tablets, Rx only, Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA, NDC 0006-0033-10 (Shellpack and Print Mat Labels), 0006-0033-30 (Carton Label)

Product Quantity:
51,320 cartons

Reason for Recall:
Failed Dissolution Specifications: potential for delayed dissolution of the dose after administration which may result in delayed release of the drug, delaying onset of sleep.

Recall Number:
D-0584-2025

Code Information:
Lots 2090019 and 2123744, Exp. 4/30/2027

Class II Drugs Event

Event ID:
97293

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
135 Us Highway 202 206 Ste 15
Bedminster, NJ 07921-2608
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Amlodipine and Olmesartan Medoxomil Tablets, 5 mg/ 40 mg, 30-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA; Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-501-30

Product Quantity:
8,568 bottles

Reason for Recall:
Failed Dissolution Specifications: low dissolution results

Recall Number:
D-0576-2025

Code Information:
Lot 23121560, Exp 4/30/2026

Class II Drugs Event

Event ID:
97334

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer
66 Hudson Blvd
Manhattan, NY 10001
United States

Distribution Pattern:
Within U.S

Associated Products

Product Description:
Levoxyl (levothyroxine sodium tablets, USP), 50 mcg, 100-count bottle, Rx only, Distributed by: Pfizer Inc., New York, NY 10017, Made in Austria, NDC 60793-851-01.

Product Quantity:
29, 004 bottles

Reason for Recall:
Subpotent drug

Recall Number:
D-0575-2025

Code Information:
Lot #: 24C11, Exp 2/28/2026.

Class II Drugs Event

Event ID:
97336

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/25/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2025

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:
NJ, AZ, IN

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60 mg, 1,000 Capsules per bottle, Rx Only, Manufactured by: Towa Pharmaceutical Europe, S.L., Martorelles, (Barcelona), Spain. Manufactured for: Quallent Pharmaceuticals Health LLC, Grand Cayman, Cayman Islands. NDC 82009-032-10

Product Quantity:
1,856 bottles

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

Recall Number:
D-0580-2025

Code Information:
Lot 240539C, Exp 1/31/2027

Class II Drugs Event

Event ID:
97368

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/14/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B BRAUN MEDICAL INC
861 Marcon Blvd
Allentown, PA 18109-9577
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Lactated Ringer's Injection USP, L 7500, 1000mL Excel Container, Rx Only, Sterile, nonpyrogenic, single dose container, B. Braun Medical Inc., Bethlehem, PA 18018, NDC 0264-7750-00.

Product Quantity:
74,088 containers

Reason for Recall:
Lack of Assurance of Sterility; potential for fluid leakage at one of the weld sites.

Recall Number:
D-0585-2025

Code Information:
Lot #: J5C802, J5C917, J5C918, Exp. 08/31/2027

Product Description:
0.9% Sodium Chloride Injection USP, L 8000, 1000mL Excel Container, Rx Only, Sterile, nonpyrogenic, single dose container, B. Braun Medical Inc., Bethlehem, PA 18018, NDC 0264-7800-00.

Product Quantity:
23,100 containers

Reason for Recall:
Lack of Assurance of Sterility; potential for fluid leakage at one of the weld sites.

Recall Number:
D-0586-2025

Code Information:
Lot #: J5C919, Exp. 08/31/2027

Class II Drugs Event

Event ID:
97370

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2025

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:
Nationwide in the USA

Associated Products

Product Description:
Carvedilol Tablets, USP, 3.125 mg, Packaged as: a)500-count bottle, NDC 68462-162-05; b) 100-count bottle, NDC 68462-162-01; Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., Mahwah, NJ, USA, NJ 07430.

Product Quantity:
44,328 bottles

Reason for Recall:
CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level.

Recall Number:
D-0577-2025

Code Information:
Lot#: a)19242274, 19242275, 19242272, Exp: 5/31/20; b) 19242272, Exp: 5/31/2026

Product Description:
Carvedilol Tablets, USP, 12.5 mg, 500-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., USA, Mahwah, NJ 07430. NDC 68462-164-05

Product Quantity:

6,432 bottles

Reason for Recall:
CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level.

Recall Number:
D-0578-2025

Code Information:
Lot#:19243202, Exp: 7/31/2026.

Product Description:
Carvedilol Tablets, USP, 25 mg, 500-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., USA, Mahwah, NJ 07430. NDC 68462-165-05

Product Quantity:
4,800 bottles

Reason for Recall:
CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level.

Recall Number:
D-0579-2025

Code Information:
Lot#:19243104, Expires: 7/31/2026.

Class II Drugs Event

Event ID:
97372

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/14/2025

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:
Nationwide within the USA

Associated Products

Product Description:
Carvedilol Tablets, USP, 12.5 mg, 500 Tablets per carton, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 47430, NDC 68462-164-05

Product Quantity:
17, 496 bottles

Reason for Recall:
CGMP Deviations: Results for N-Nitroso Carvedilol Impurity-1 (NNCI) impurity observed to be above the FDA-recommended limit of NMT 4.0 ppm

Recall Number:
D-0587-2025

Code Information:
Lot #: 17241257, 17241258, 17241279, Exp. Date 06/2026

Product Description:
Carvedilol Tablets, USP, 25 mg, 500 Tablets per carton, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 47430 NDC: 68462-165-05

Product Quantity:
14,976 bottles

Reason for Recall:
CGMP Deviations: Results for N-Nitroso Carvedilol Impurity-1 (NNCI) impurity observed to be above the FDA-recommended limit of NMT 4.0 ppm

Recall Number:
D-0588-2025

Code Information:
Lot #: 17241213, 17241215, 17241224, Exp. Date 06/2026

Class II Drugs Event

Event ID:
97395

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2025

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Westminster Pharmaceuticals LLC
1321 Murfreesboro Pike Ste 607
Nashville, TN 37217-2693
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Metoprolol Tartrate Tablets, USP, 50 mg, 1000 Tablets, Rx Only, Manufactured by: Renata PLC (General Plant -2), Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, 1700 Bangladesh, Distributed by: Westminster Pharmaceuticals, LLC, Nashville, TN 37217, NDC 69367-354-10

Product Quantity:
16,672 1000-count bottles

Reason for Recall:
CGMP Deviations: Presence of a nitrosamine, N-nitroso-metoprolol above the established Acceptable Daily Intake (ADI) level.

Recall Number:
D-0581-2025

Code Information:
Batch # R55230021, R55230031, R55230041, Exp Date: 9/30/25; Batch # R55230051, R55230061, R55230071, R55230081, R55230091, R55230101, R55230111, R55230121, R55230131, R55230141, Exp Date: 10/31/2025; Batch # R55230151, Exp Date: 11/30/25; Batch # R55240011, Exp Date: 12/31/25; Batch # R55240021, R55240031, R55240041, R55240051, R55240061, Exp Date: 6/30/26; Batch # R55240071, R55240081, R55240091, R55240101, R55240111, R55240121, Exp Date: 7/31/26

Product Description:
Metoprolol Tartrate Tablets, USP, 100 mg, 1000 Tablets, Rx Only, Manufactured by: Renata PLC (General Plant -2), Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, 1700 Bangladesh, Distributed by: Westminster Pharmaceuticals, LLC, Nashville, TN 37217, NDC 69367-355-10

Product Quantity:
4,456 1000-count bottles

Reason for Recall:
CGMP Deviations: Presence of a nitrosamine, N-nitroso-metoprolol above the established Acceptable Daily Intake (ADI) level.

Recall Number:
D-0582-2025

Code Information:
Batch # R56240011, Exp Date: 2/28/26; Batch # R56240021, R56240031, Exp Date: 3/31/26; Batch # R56240041, R56240051, R56240061, Exp Date: 4/30/26; Batch # R56240071, Exp Date: 7/31/26

Class II Drugs Event

Event ID:
97406

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/08/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2025

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:
Theophylline extended-release tablets 400mg, 100-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Colvale-Bardez, Goa- 403513 India, Manufactured for: Glenmark Pharmaceuticals Inc. USA, Mahwah, NJ, NDC 68462-380-01

Product Quantity:
22,656 bottles

Reason for Recall:
Failed Dissolution Specifications: Failure results (above) were reported for the Dissolution (by UV) test for commercial annual stability at the long-term shelf life stability interval, wherein the dissolution results do not comply with L3 stage dissolution criteria.

Recall Number:
D-0583-2025

Code Information:
Batch # 19243193, 19243215, 19243231,19243248, 19243283, Exp 7/31/2026; 19244530, 19244561, Exp 10/31/2026; 19250178, Exp 12/31/2026