Enforcement Report - Week of February 12, 2025

Class I Drugs Event

Event ID:
96013

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/05/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
ENDO USA, Inc.
870 Parkdale Rd
Rochester, MI 48307-1740
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Adrenalin Chloride Solution (Epinephrine Nasal Solution, USP), 30mg/30mL (1mg/mL), packaged in 30 mL vials, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 42023-103-01

Product Quantity:
44,397 amber glass vials

Reason for Recall:
Labeling: Not Elsewhere Classified: misleading label similar in appearance to the FDA-approved drug product Adrenalin¿ (epinephrine injection, USP)

Recall Number:
D-0223-2025

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
96115

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Granix (tbo-filgrastim) Injection 300 mcg/0.5 mL, Single Dose prefilled syringe, packaged as a) 1 syringe in 1 CARTON, NDC 63459-910-11, Blister NDC 63459-910-12; (b)10 syringes in 1 CARTON, NDC 63459-910-15, Blister NDC 63459-910-12; (c) 1 syringe in 1 CARTON, NDC 63459-910-17 without safety guard and blister, Rx Only, Manufactured by: UAB Teva Baltics, Vilnius, Lithuania. Distributed by Teva Pharmaceuticals USA, Inc. North Wales PA 19454. Product of Israel.

Product Quantity:
34,636 cartons

Reason for Recall:
Failed Stability Specifications - 12-month stability test result for one of the known peptides is below the specification limit

Recall Number:
D-0218-2025

Code Information:
Lot # (a) 135738, (b) 137149, (c) 137148, Exp. date 09/30/2025

Class II Drugs Event

Event ID:
96159

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2025

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
SKY PACKAGING
4835 Crumpler Rd Ste B
Memphis, TN 38141
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
HydrALAZINE Hydrochloride, 25 mg, 100 Unit Dose Tablets (10x10), USP, Rx only, Manufactured by Strides Pharma Science Ltd, Bengaluru, India, Distributed by McKesson by: McKesson Corporation dba SKY Packaging, TN 38141. NDC 63739-327-10

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0219-2025

Code Information:
Lot #: 0000127312, Exp. Date 31-Mar-2025; 0000127576, 0000127577, Exp. Date 31-Jul-2025; 0000128204, Exp. Date 31-Dec-2025; 0000128358, Exp. Date 31-Jan-2026

Product Description:
HydrALAZINE Hydrochloride, 100 Tablets (10x10), USP, 50mg, Rx only, Manufactured by Strides Pharma Science Ltd, Bengaluru, India, Distributed by McKesson by: McKesson Corporation dba SKY Packaging, TN 38141. NDC 63739-328-10

Product Quantity:

N/A

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0220-2025

Code Information:
Lot #: 0000127410, 63739-328-10, Exp. Date 30-Apr-2025; 0000127579, Exp. Date 31-Aug-2025; 0000128245, Exp. Date 31-Dec-2025; 0000128486, Exp. Date 28-Feb-2026.

Class II Drugs Event

Event ID:
96162

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/03/2025

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 U.S

Associated Products

Product Description:
Carvediol Tablets, USP, 25 mg, Rx only, a)500 Tablets, NDC 68462-165-05; b) 100 Tablets, NDC 68462-165-01, Manufactured for Glenmark Pharmaceuticals, NJ.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit.

Recall Number:
D-0215-2025

Code Information:
Lot numbers: a) 17230500, 17230509,17230526,17230546,17230551,17230603,17230628, 17230642,17230645,17230681, Exp.:02/2025; 17230829,17230832,17230854, 17230864,17230874,17230876,17230889,17230894, Exp.: 03/2025; 17230960, 17230964,17230976,17230981,17230985,17231161,17231171, Exp.: 04/2025 17231315,17231318,17231332,17231333,17231365, Exp.: 05/2025; 17231539, 17231563, Exp.: 06/2025; 17231653,17231662,17231663,17231680,17231691, 17231781,17231782,17231789, Exp.: 07/2025;17231838,17231880, Exp.: 08/2025; 17232144,17232147,17232151, Exp.: 09/2025; 17232369,17232370,17232408,17232409, 17232416,17232504,17232522,17232531,17232538,17232543, Exp.: 11/2025; 17240377,17240385,17240415,17240422,17240430,17240510, Exp.: 02/2026. b) 17230551, 17240377, Exp.:02/2025

Product Description:
Carvediol Tablets, USP, 12.5 mg, Rx only, a)500 Tablets, NDC 68462-164-05; b) 100 Tablets, NDC 68462-164-01, Manufactured for Glenmark Pharmaceuticals, NJ.

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit.

Recall Number:
D-0216-2025

Code Information:
Lot numbers: a) 17230658, Exp.: 02/2025; 17230814,17230822, Exp.: 03/2025; 17231004,17231009,17231022, Exp.: 04/2025; 17231393,17231392, Exp.: 05/2025; 17231538, 17231541,17231542, Exp.: 06/2025; 17231710,17231718,17231721,17231722,17231730, Exp': 07/2025; 17232169, Exp.: 09/2025; 17232253, Exp.: 10/2025; 17240220,17240240, Exp.: 01/2026; 17240459, Exp.: 02/2026 b) 17230814, Exp.: 03/2025; 17231392, Exp.:05/2025; 17232260, Exp.: 10/2025.

Class II Drugs Event

Event ID:
96191

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/03/2025

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:
FL

Associated Products

Product Description:
Carvedilol 25 mg Tablet, QTY: 30 Tablets per Blister Pack (3 x 10 blister cards), Rx Only, MFG by: Glenmark, Mahwah, NJ 07430, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC: 70518-3945-00.

Product Quantity:
247 blister packs

Reason for Recall:
CGMP deviations: presence of N-Nitroso Carvedilol Impurity-1 (NNC 1), above the FDA recommended acceptable intake limit.

Recall Number:
D-0217-2025

Code Information:
Lot #s: J0777493050824, Exp. 5/31/2025; J0787856062124, Exp. 7/31/2025.

Class II Drugs Event

Event ID:
96196

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/23/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/31/2025

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:
Distributed to one (1) Us Distributor in NJ

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 5mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-514-05.

Product Quantity:
118104 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-0214-2025

Code Information:
Lot#: 083J033, Exp. Date 09/2025

Class II Drugs Event

Event ID:
96201

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/30/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne, TN 37086-3606
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Potassium Chloride Extended-Release Tablets, USP, 10 mEq (750 mg), 100 Tablets per carton (10 x 10 unit dose blisters), Rx Only, Distributed by: Aurobindo Pharma USA< INC., 279 Princeton-Hightstown Road, East Windsor, NJ 08520. Made in India. Distributed by: MAJOR PHARMACEUTICALS, Livonia, MI 48152. NDC: 0904-7216-61

Product Quantity:
6997 cartons

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:
D-0221-2025

Code Information:
Lot# T05224; Exp. 02/2026

Class III Drugs Event

Event ID:
96119

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAI Holdings, LLC. dba Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville, SC 29605-5252
United States

Distribution Pattern:
OH

Associated Products

Product Description:
Guaifenesin and Codeine Phosphate Oral Solution USP, 100mg/10 mg per 5 mL, 16 fl oz (473 ml) bottles, PAI Pharmaceutical Associates, Inc., Greenville, SC 29605, NDC 0121-0775-16

Product Quantity:
4080 Bottles

Reason for Recall:
Superpotent; sodium benzoate preservative

Recall Number:
D-0222-2025

Code Information:
Lot number 4B07, Exp Date: 2026-OCT-31