Enforcement Report - Week of December 18, 2024

Class II Drugs Event

Event ID:
95768

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg, PA 15317-5853
United States

Distribution Pattern:
Nationwide within the United States and Puerto Rico

Associated Products

Product Description:
Levothyroxine Sodium Tablets USP, 125 mcg, packaged in a) 90-count bottles (NDC 0378-1813-77) and b) 1000-count bottles (NDC 0378-1813-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
92,512 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0118-2025

Code Information:
Lot #: a) 3182797, Exp. Date Nov 2024; 8177587, b) 3199816, Exp. Date Jun 2025

Product Description:
Levothyroxine Sodium Tablets USP, 137 mcg, packaged in a) 90-count bottles (NDC 0378-1823-77) and b) 1000-count bottles (NDC 0378-1823-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
118,324 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0119-2025

Code Information:
Lot #: a) 8165919, Exp. Date Dec 2024; 8172050, Exp. Date Mar 2025; 8183251, Exp. Date Sept 2025 b) 3185542, Exp. date Dec 2024; 3192838, Exp. Date Mar 2025; 3208172, Exp. Date Sept 2025

Product Description:
Levothyroxine Sodium Tablets USP, 150 mcg, packaged in a) 90-count bottles (NDC 0378-1815-77) and b) 1000-count bottles (NDC 0378-1815-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
9,828 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0120-2025

Code Information:
Lot #: a) 8177720, Exp. Date Jun 2025; b) 3200218, Exp. Date Jun 2025

Product Description:
Levothyroxine Sodium Tablets USP, 175 mcg, packaged in a) 90-count bottles (NDC 0378-1817-77) and b) 1000-count bottles (NDC 0378-1817-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
19, 549 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0121-2025

Code Information:
Lot #: a) 3192915, 8172108, Exp. Date Mar 2025; b) 3208680, Exp. Date Sep 2025

Product Description:
Levothyroxine Sodium Tablets USP, 200 mcg, packaged in a) 90-count bottles (NDC 0378-1819-77) and b) 1000-count bottles (NDC 0378-1819-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
55,032 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0122-2025

Code Information:
Lot #: a)8179847, Exp. Date July 2025; b) 3203518, Exp. Date July 2025

Product Description:
Levothyroxine Sodium Tablets USP, 25 mcg, packaged in a) 90-count bottles (NDC 0378-1800-77) and b) 1000-count bottles (NDC 0378-1800-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
34,845 bottes

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0123-2025

Code Information:
Lot #: a) 8181875, Exp. Date Aug 2025; 8174497, Exp. Date April 2025 b) 3209099, Exp. Date Sep 2025; 3206534, Exp. Date Aug 2025; 3196137, Exp. Date April 2025

Product Description:
Levothyroxine Sodium Tablets USP, 50 mcg, packaged in a) 90-count bottles (NDC 0378-1803-77) and b) 1000-count bottles (NDC 0378-1803-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
42,331 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0124-2025

Code Information:
Lot #: a) 8174701, Exp. Date April 2025; 8182228, Exp. Date Aug 2025 b)3193984, Exp. Date Mar 2025; 3206790, Exp. Date Aug 2025

Product Description:
Levothyroxine Sodium Tablets USP, 75 mcg, packaged in a) 90-count bottles (NDC 0378-1805-77) and b) 1000-count bottles (NDC 0378-1805-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
63,077 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0125-2025

Code Information:
Lot #: a) 8177078, Exp. Date May 2025; 8168596, Exp. Date Jan 2025 b) 3199313, Exp. Date May 2025; 3194118, Exp. Date Mar 2025; 3186238, Exp. Date Dec 2024; 3209590, Exp. Date Sep 2025; 3199317, Exp. Date May 2025; 3188733, Exp. Date Jan 2025

Product Description:
Levothyroxine Sodium Tablets USP, 88 mcg, packaged in a) 90-count bottles (NDC 0378-1807-77) and b) 1000-count bottles (NDC 0378-1807-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
43,765 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0126-2025

Code Information:
Lot # a) 8180781, Exp. Date Aug 2025; b)3191628, Exp. Date Feb 2025; 3197139, Exp. Date Apr 2025; 3188976, Exp. Date Jan 2025; 3184929, Exp. Date Dec 2024; 3204909, Exp. Date Aug 2025

Product Description:
Levothyroxine Sodium Tablets USP, 100 mcg, packaged in a) 90-count bottles (NDC 0378-1809-77) and b) 1000-count bottles (NDC 0378-1809-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
65,169

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0127-2025

Code Information:
Lot #: a) 8171269, Exp. Date Feb 2025; 8179579, Exp. Date July 2025 b)3183815, Exp. Date Nov 2024; 3189147, Exp. Date Jan 2025; 3192027, Exp. Date Feb 2025; 3202894, Exp. Date Jul 2025; 3192026, Exp. Date Feb 2025; 3199781, Exp. Date Jun 2025. 3192028, exp. date Feb 2025 3202895, exp. date July 2025

Product Description:
Levothyroxine Sodium Tablets USP, 112 mcg, packaged in a) 90-count bottles (NDC 0378-1811-77) and b) 1000-count bottles (NDC 0378-1811-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.

Product Quantity:
35,883 bottles

Reason for Recall:
Superpotent Drug and Subpotent Drug: potency failures obtained

Recall Number:
D-0128-2025

Code Information:
Lot #: a) 8171623, Exp. Date Feb 2025; 8164486, Exp. Date Nov 2024 b)3205462, Exp. Date Aug 2025; 3192428, Exp. Date Feb 2025; 3184096, Exp. Date Nov 2024

Class II Drugs Event

Event ID:
95773

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LNK International, Inc.
22 Arkay Dr
Hauppauge, NY 11788-3708
United States

Distribution Pattern:
Product was distributed to 1 wholesale retail customer who may have further distribute the product nationwide.

Associated Products

Product Description:
Kirkland Severe Cold & Flu Plus Congestion: Day - 112 coated caplets blister pack; (Acetaminophen 325mg, Dextromethorphan HBr 10 mg, Guaifenesin 200 mg, Phenylephrine HCl 5 mg); Night - 56 coated caplets blister pack; (Acetaminophen 325mg, Dextromethorphan HBr 10 mg, Doxylamine succinate 6.25 mg, Phenylephrine HCl 5 mg); Manufactured BY: LNK International, Inc. FOR: Costco Wholesale Corporation. NDC# 63981-795-81

Product Quantity:
288 cases x 30 8,640 boxes

Reason for Recall:
CGMP Deviations: Released product should have been rejected.

Recall Number:
D-0115-2025

Code Information:
Lot # P139953, exp. date 2026/AUG Lot # P139815, exp. date 2026/AUG

Class II Drugs Event

Event ID:
95817

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc.
1718 Northrock Ct
Rockford, IL 61103-1201
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP, 100 mcg (0.1 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-442-20

Product Quantity:
2,835 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0131-2025

Code Information:
Lot #: 3115936, Exp. Date 07/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 112 mcg (0.112 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-039-20

Product Quantity:
988 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0132-2025

Code Information:
Lot #: 3115707, Exp. Date 02/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 125 mcg (0.125 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-443-20

Product Quantity:
1,664 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0133-2025

Code Information:
Lot #: 3115893, Exp. Date 6/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 137 mcg (0.137 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-041-20

Product Quantity:
1,133 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0134-2025

Code Information:
Lot #: 3115448, Exp. Date 12/31/2024;3115732, Exp. Date 3/31/2025; 3116024, Exp. Date 9/30/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 150 mcg (0.150 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-445-20

Product Quantity:
690 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0135-2025

Code Information:
Lot #: 3115924, Exp. Date 06/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 175 mcg (0.175 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-040-20

Product Quantity:
205 cartons

Reason for Recall:
Subpotent and Superpotent Drug

Recall Number:
D-0136-2025

Code Information:
Lot #: 3115869, Exp. Date 03/2025

Class II Drugs Event

Event ID:
95830

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/11/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Medical-Surgical Inc. Corporate Office
9954 Maryland Drive Deep Run Iii Ste. 4000
Richmond, VA 23233
United States

Distribution Pattern:
Virgina

Associated Products

Product Description:
Hylenex recombinant (hyaluronidase) injection, 150 USP units/mL, 4x1 mL Single Dose Vials, Rx only, Manufactured for and marketed by Halozyme, Inc., 12390 El Camino Real San Diego California 92130, Distributed by Antares Pharma, Inc., Ewing, NJ NDC 18657-117-04

Product Quantity:
5 cartons/20 units each carton

Reason for Recall:
cGMP Deviations: Temperature excursion

Recall Number:
D-0116-2025

Code Information:
Serial # 100000831961 100000820688 100000820689 100000820515

Class II Drugs Event

Event ID:
95896

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany, NJ 07054-3707
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Dabigatran Etexilate, 75 mg capsules, 60-count bottles, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-474-60

Product Quantity:
12,092 bottles

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

Recall Number:
D-0129-2025

Code Information:
Lot #: 24142328, 24142329, 24142330, Exp. Date May 31, 2026.

Product Description:
Dabigatran Etexilate, 150mg capsules, 60-count bottles, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-475-60

Product Quantity:
N/A

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

Recall Number:
D-0130-2025

Code Information:
Lot #: 24142192, 24142193, 24142194, Exp. Date April 30, 2026; 24142463, Exp. Date May 31, 2026;

Class II Drugs Event

Event ID:
95921

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2024

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:
Distributed to one Us Distributor in NJ.

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution USP, 0.25%, Sterile, 15mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-513-15.

Product Quantity:
5184 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-0114-2025

Code Information:
Lot #: 083I006, Exp 08/31/2025

Class III Drugs Event

Event ID:
95811

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Javygtor (sapropterin dihydrochloride) Tablets 100mg, 120-count bottle, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 Made in India, NDC 43598-096-04.

Product Quantity:
7,233 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: The observed impurity level was 0.15%, exceeding the specification limit of not more than 0.12%.

Recall Number:
D-0117-2025

Code Information:
Lot #: T2300653, Exp 01/31/2025; T2303956, T2303750, Exp 06/30/2025; T2304190, T2304987, Exp 08/31/2025; T2302026, Exp 03/31/2025; T2302526, Exp 05/31/2025.

Class III Drugs Event

Event ID:
95820

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/15/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Biocompatibles UK, Ltd.
Chapman House Farnham Business Park; Weydon Lane
Farnham
United Kingdom

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Varithena (polidocanol injectable foam)Administration Pack, Contains: 3 silicone-free syringes, 2 compression pads, 1 Varithena Transfer Unit, 1 manometer tubing, Rx Only, Distributed by Biocompatibles Inc., a BTG International Group company. CN01114.3

Product Quantity:
432 administration packs

Reason for Recall:
Defective Delivery System: incorrect silicone oil-free NormJect 10 mL Luer Lock Solo syringes packaged in the pack, instead of the required silicone oil-free NormJect 10 mL Luer Solo syringes (luer slip connection).

Recall Number:
D-0113-2025

Code Information:
Lot # 34067418, Exp. March 2026, 34067419, Exp. March 2026