Enforcement Report - Week of November 27, 2024

Class II Drugs Event

Event ID:
95610

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore, MD 21202-6174
United States

Distribution Pattern:
Product was distributed to 30 wholesalers/distributors who may have further distributed the product nationwide.

Associated Products

Product Description:
Ramipril Capsules USP 2.5 mg, a) 90 count (NDC 68180-589-09), b) 100 count NDC 68180-589-01), and c) 500 count (NDC 68180-589-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India

Product Quantity:
112,770 bottles

Reason for Recall:
CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor

Recall Number:
D-0052-2025

Code Information:
a) NDC 68180-589-09; Lots G326781, exp. date 30-Sep-25, GA04468, exp. date 31-May-25 b) NDC 68180-589-01; Lots G326763, exp. date 30-Sep-25, GA03041, exp. date 31-Mar-26, GA03725, exp. date 30-Apr-26, GA04402, exp. date 31-May-26, c) NDC 68180-589-02; Lots G326782, exp. date 30-Sep-25, GA04462, exp. date 31-May-26

Product Description:
Ramipril Capsules USP 5 mg, a) 90 count (NDC 68180-590-09), b) 100 count NDC 68180-590-01), and c) 500 count (NDC 68180-590-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India

Product Quantity:
146,322 bottles

Reason for Recall:
CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor

Recall Number:
D-0053-2025

Code Information:
a) NDC 68180-590-09; Lots G326928, exp. date 30-Sep-25, GA00964, exp. date 31-Dec-25, b) NDC 68180-590-01, Lots G326897, G326929, exp. date 30-Sep-25, GA00854, GA00933, GA00954, exp. date 31-Dec-25, c) NDC 68180-590-02, Lot GA00955, exp. date 31-Dec-25

Product Description:
Ramipril Capsules USP 10 mg, a) 90 count (NDC 68180-591-09), b) 100 count NDC 68180-591-01), and c) 500 count (NDC 68180-591-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India

Product Quantity:

357,414 bottles

Reason for Recall:
CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor

Recall Number:
D-0054-2025

Code Information:
a) NDC 68180-591-09; Lots G327086, exp. date 30-Sep-25 GA01065, exp. date 31-Dec-25, b) NDC 68180-591-01 Lots G325033, G324987, exp. date 31-Jul-25, G325110, GA00956, GA01066, GA01126, exp. date 31-Dec-25, GA03299, GA03288, GA03287, exp. date 31-Mar-26 c) NDC 68180-591-02 Lot GA05919, exp. date 31-Jul-26 G327131, exp. date 30-Sep-25

Class II Drugs Event

Event ID:
95659

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/11/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Safecor Health, LLC
317 New Boston St
Woburn, MA 01801-6231
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Vitamin D3, 25 mcg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-104-01

Product Quantity:
7488 boxes

Reason for Recall:
cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.

Recall Number:
D-0056-2025

Code Information:
Lot# 24A0052, exp. date 05/01/2026; 24A0057, exp. date 05/13/2026; 24A0066, exp. date 05/31/2026; 24A0067, exp. date 06/04/2026; 24A0068, exp. date 06/17/2026; 24A0069, exp. date 06/19/2026 24A0075, exp. date 07/08/2026 24A0078, exp. date 07/12/2026

Product Description:
Vitamin B1, 100 mcg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-108-01

Product Quantity:
3139 boxes

Reason for Recall:
cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.

Recall Number:
D-0057-2025

Code Information:
Lot# 24A0050, exp. date 04/25/2026; 24A0055, exp. date 05/09/2026; 24A0059, exp. date 05/16/2026; 24A0060, exp. date 05/20/2026; 24A0071, exp. date 06/24/2026; 24A0072, exp. date 06/26/2026

Product Description:
Aspirin Chewable tablet 81 mg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-129-01

Product Quantity:
1470 boxes

Reason for Recall:
cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.

Recall Number:
D-0058-2025

Code Information:
Lot# 24A0061, exp. date 05/23/2026

Product Description:
Calcium Carbonate Chewable 500 mg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-106-01

Product Quantity:
791 boxes

Reason for Recall:
cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.

Recall Number:
D-0059-2025

Code Information:
Lot# 24A0073, exp. date 06/28/2026

Product Description:
Docusate Sodium 250 mg, 1 Softgel in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-101-01

Product Quantity:
587 boxes

Reason for Recall:
cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.

Recall Number:
D-0060-2025

Code Information:
Lot# 34A0054, exp. date 05/07/2026

Class II Drugs Event

Event ID:
95701

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/31/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami, FL 33186-6109
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Xelstrym (dextroamphetamine) transdermal system, 13.5 mg dextroamphetamine/9 hours, 30 individually sealed transdermal patches, inside a foil-sealed polypropylene tray, packed in a paper carton/box, MANUFACTURED BY NOVEN PHARMACEUTICALS, INC., Miami, FL 33186 United Sates, NDC 68968-0215-3

Product Quantity:
685 boxes

Reason for Recall:
Defective Delivery System: The product does not meet predetermined specifications for Coldflow (adhesive).

Recall Number:
D-0055-2025

Code Information:
Lot # 95598, Exp 02/28/25

Class II Drugs Event

Event ID:
95705

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/18/2024

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 within the United States

Associated Products

Product Description:
Guaifenesin Dextromethorphan Syrup, 200 mg/20mg per 10 mL, Major Pharmaceuticals 8401 Bearing Drive, Suite 100, Indianapolis, IN, 46268, NDC 0904-7135-72

Product Quantity:
N/A

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0049-2025

Code Information:
Lot #: C00128, Exp. Date 04/2025; C00146, Exp.Date 07/2025

Product Description:
Guaifenesin Dextromethorphan Syrup, 100 mg/10mg per 5 mL, Major Pharmaceuticals 8401 Bearing Drive, Suite 100, Indianapolis, IN, 46268, NDC 0904-7134-70

Product Quantity:
N/A

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0050-2025

Code Information:
Lot #: C00113, Exp. Date 11/2024; C00125, Exp. Date 04/2025; C00145, Exp. Date 07/2025

Class II Drugs Event

Event ID:
95718

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/18/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MEDIVANT HEALTHCARE
158 S Kyrene Rd
Chandler, AZ 85226
United States

Distribution Pattern:
Nationwide Within U.S.

Associated Products

Product Description:
BEVACIZUMAB (AVASTIN)1.25mg/0.05mL, Sterile Injection, 0.5 mL Single-Dose Syringe, Rx Only, Repackaged by: Medivant Healthcare: 24416 N 19th Ave, Phoenix, AZ, NDC 81483-0041-1

Product Quantity:
27,560 Syringes

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-0051-2025

Code Information:
Lot #: D24005, Exp. Date 20 February 2025; D24006, Exp. Date 21 February 2025; D24007, Exp. Date 22 February 2025; D24008, Exp. Date 19 March 2025; D24009, Exp. Date 20 March 2025; D24012, Exp. Date 25 April 2025.

Class II Drugs Event

Event ID:
95749

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/15/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/20/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Evaric Pharmaceuticals Inc.
155 Commerce Dr
Hauppauge, NY 11788-3925
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lisinopril Tablets, USP 10 mg, 90 tablets per bottle, Rx Only, Distributed by: Walmart, Bentonville, AR 72716, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045, NDC# 68645-610-90.

Product Quantity:
222, 600 bottles

Reason for Recall:
Presence of Foreign Object: A pharmacist discovered a metal fragment embedded in a lisinopril 10 mg tablet.

Recall Number:
D-0061-2025

Code Information:
Lot #: 241103, exp. date 05/31/2026

Class III Drugs Event

Event ID:
95620

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/15/2024

Initial Firm Notification of Consignee or Public:
N/A

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
IBU (ibuprofen) 600 mg tablets, 500-count bottle, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-683-05

Product Quantity:
3416 botttles

Reason for Recall:
Failed Tablet/Capsule Specifications

Recall Number:
D-0047-2025

Code Information:
Lot #: C5406201, Exp 03/31/2028

Class III Drugs Event

Event ID:
95736

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/11/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/18/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Padagis US LLC
3940 Quebec Ave N
Minneapolis, MN 55427-1244
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Triamcinolone Acetonide Cream USP, 0.025%, 1 LB (454 g) per jar, Rx Only, Manufactured By Padagis, Minneapolis, MN 55427. NDC: 45802-0063-05

Product Quantity:
10,872 jars

Reason for Recall:
Subpotent and Superpotent Drug. Out of specification assay results recorded as part of Uniformity of Container test during long-term stability testing.

Recall Number:
D-0048-2025

Code Information:
Lot #: 2024154238, 2024174344, Exp. Date 3/31/2026