Enforcement Report - Week of February 14, 2024

Class I Drugs Event

Event ID:
93357

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/05/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Kilitch Healthcare India Limited
R - 904 905 T T C Industrial Road
Navi Mumbai India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
CVS Health brand Lubricant Eye Drops (Carboxymethylcellulose Sodium 0.5%), packaged in a) 0.5 FL OZ (15mL) bottles (Single Pack) (NDC 76168-702-15) and b) 0.5 FL OZ (15 mL) bottles (Twin pack) (NDC 76168-702-30), Distributed by: CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895.

Product Quantity:
386,256 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0290-2024

Code Information:
All lots

Product Description:
Leader brand Lubricant Eye Drops (Carboxymethylcellulose Sodium 0.5%), packaged in a) 0.5 FL OZ (15mL) bottles (Single Pack) (NDC 70000-0090-1) and b) 0.5 FL OZ (15 mL) bottles (Twin pack) (NDC 70000-0090-2), Distributed by: Cardinal Health Dublin, Ohio 43017

Product Quantity:
210,192 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0291-2024

Code Information:
All lots

Product Description:
CVS Health brand Lubricant Eye Drops (Propylene glycol 0.6%), packaged in a) 0.33 FL OZ (10mL) bottles (Single Pack) (NDC 76168-714-10) and b) 0.33 FL OZ (10 mL) bottles (Twin pack) (NDC 76168-714-20), Distributed by: CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895.

Product Quantity:
137,784 bottles

Reason for Recall:

Non-Sterility

Recall Number:
D-0292-2024

Code Information:
All lots

Product Description:
Rugby brand Polyvinyl Alcohol 1.4% Lubricating Eye Drops, packaged in 0.5 FL OZ (15 mL) bottles, Distributed by: Rugby Laboratories, Livonia, MI 48152, NDC 0536-1325-94

Product Quantity:
1,492,344 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0293-2024

Code Information:
All lots

Product Description:
CVS Health brand Lubricating Gel Drops (Polyethylene glycol 400 0.4% and Propylene glycol 0.3%), packaged in 0.33 FL OZ (10 mL) bottles, Distributed by: CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895. NDC 76168-712-10

Product Quantity:
110,832 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0294-2024

Code Information:
All lots

Product Description:
Leader brand Dry Eye Relief (Polyethylene glycol 400 0.4% and Propylene glycol 0.3%) packaged in 0.33 FL OZ (10 mL) bottles, Distributed by Cardinal Health Dublin, Ohio 43017, NDC 70000-0088-1

Product Quantity:
12,960 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0295-2024

Code Information:
All lots

Product Description:
CVS brand Multi Action Relief Drops (Polyvinyl alcohol 0.5%, Povidone 0.6%, Tetrahydrozoline 0.05%) packaged in 0.5 FL OZ (15mL) bottles, Distributed by CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895. NDC 76168-706-15

Product Quantity:
253,080 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0296-2024

Code Information:
All lots

Product Description:
Leader brand Eye Irritation Relief (Polyvinyl alcohol 0.5%, Povidone 0.6%, Tetrahydrozoline 0.05%), packaged in 0.5 FL OZ (15 mL) bottles, Cardinal Health Dublin, Ohio 43017, NDC 70000-0087-1

Product Quantity:
10,944 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0297-2024

Code Information:
All lots

Product Description:
CVS Health brand, Lubricant Gel Drops (Carboxymethylcellulose Sodium 1%) packaged in a) 0.5 FL OZ (15mL) bottles (Single Pack) (NDC 76168-704-15) and b) 0.5 FL OZ (15 mL) bottles (Twin pack) (NDC 76168-704-30), Distributed by: CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895.

Product Quantity:
150,720 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0298-2024

Code Information:
All lots

Product Description:
Leader brand Dry Eye Relief (Carboxymethylcellulose Sodium 1%), packaged in 0.5 FL OZ (15 mL) bottles, Cardinal Health Dublin, Ohio 43017, NDC 70000-0089-1

Product Quantity:
23,208 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0299-2024

Code Information:
All lots

Product Description:
Target brand High Performance Lubricant Eye Drops (Polyethylene glycol 400 0.4%, Propylene glycol 0.3%) a) 0.5 FL OZ (15mL) bottles (Single Pack) (NDC 11673-522-15) and b) 0.5 FL OZ (15 mL) bottles (Twin pack) (NDC 11673-522-30), Distributed by: Target Corporation Minneapolis, MN 55403

Product Quantity:
401,568 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0300-2024

Code Information:
All lots

Product Description:
Leader brand Lubricant Eye Drops (Propylene glycol Eye Drops 0.6%), packaged in 0.33 FL OZ (10 mL) bottles, Cardinal Health Dublin, Ohio 43017, NDC 70000-0587-1

Product Quantity:
14,784 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0301-2024

Code Information:
All lots

Product Description:
Velocity Pharma brand Lubricating Eye Drop (Propylene glycol Eye Drops 0.6%), packaged in 3 bottles of 0.33 FL OZ (10 mL) each, Velocity Pharma, NDC 76168-502-30

Product Quantity:
2,820 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0302-2024

Code Information:
All lots

Product Description:
EQUATE brand Hydration PF Lubricant Eye Drops (Polyethylene glycol 400 0.4% and Propylene glycol 0.3%) packaged in 0.34 FL OZ (10 mL) bottles, Distributed by: Walmart Inc., Bentonville, AR 72712, NDC 79903-168-01

Product Quantity:
33,984 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0303-2024

Code Information:
All lots

Product Description:
LUBRICANT EYE DROPS (Carboxymethylcellulose Sodium 0.5%), packaged 0.5 FL OZ (15mL) bottles (Twin Pack), Distributed by: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-4811-5

Product Quantity:
6,024 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0304-2024

Code Information:
All lots

Product Description:
CVS Health brand Mild Moderate Lubricating Eye Drops (Propylene glycol 400 0.25%), packaged in 0.5 FL OZ (15 mL) bottles, Distributed by: CVS Pharmacy Inc. One CVS Drive Woonsocket, RI 02895. NDC 76168-711-15

Product Quantity:
45,408 bottles

Reason for Recall:
Non-Sterility

Recall Number:

D-0305-2024

Code Information:
All lots

Product Description:
Lubricant Gel Drops (Carboxymethylcellulose sodium 1.0%), packaged in 0.5 FL OZ (15 mL) bottles, Distributed by: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-4540-5

Product Quantity:
7,200 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0306-2024

Code Information:
All lots

Product Description:
Lubricant Gel Drops (Polyethylene glycol 400 0.4%, Propylene glycol 0.3%), packaged in 0.33 FL OZ (10 mL) bottles, Distributed by: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-4540-3

Product Quantity:
7,776 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0307-2024

Code Information:
All lots

Product Description:
Multi-action Relief Drops (Polyvinyl alcohol 0.5%, Providone 0.6%, Tetrahydrozoline Hydrochloride 0.05%), packaged in 0.5 FL OZ (15 mL) bottles, Distributed by: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-2254-3

Product Quantity:
9,216 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0308-2024

Code Information:
All lots

Product Description:
Lubricant Eye Drops (Propylene glycol 0.6%), packaged in 0.33 FL OZ (10 mL) each bottle (Twin Pack), Distributed by: Rite Aid 30 Hunter Lane, Camp Hill, PA 17011, NDC 11822-4811-3 Retail Labeler: Rite Aid

Product Quantity:
7,296 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0309-2024

Code Information:
All lots

Product Description:
Rugby brand Lubricating Tears Eye Drops (Dextran 70 0.1%, Hypromellose 2910 0.3%), packaged in 0.5 FL OZ (15 mL) bottles, Distributed by:

Rugby Laboratories, Livonia, MI 48152, NDC 0536-1282-94

Product Quantity:
56,520 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0310-2024

Code Information:
All lots

Product Description:
Up&Up brand dry eye relief (Carboxymethylcellulose 0.5%) packaged in 0.5 FL OZ (15 mL) each bottles (Twin Pack), Distributed by: Target Corporation Minneapolis, MN 55403, NDC 76168-800-30

Product Quantity:
137,544 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0311-2024

Code Information:
All lots

Class II Drugs Event

Event ID:
93813

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/15/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Phenoxybenzamine Hydrochloride Capsules, USP 10mg, 100-count bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd, Oral Solid Dosage Unit, Ahmedabad 382213, India, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807, NDC 60219-1502-01

Product Quantity:
858 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification for unknown impurity.

Recall Number:
D-0319-2024

Code Information:
Lot # AM221153, Exp. date 06/30/2024; AM230497, Exp. date 02/29/2025

Class II Drugs Event

Event ID:
93846

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MEDLINE INDUSTRIES, LP - Northfield
3 Lakes Dr
Northfield IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Medline Remedy Clinical TREAT Antifungal Cream, 2% Miconazole Nitrate, Paraben Free, 4 FL OZ (118 mL) tube, Manufactured for Medline Industries, LP Three Lakes Drive, Northfield, IL 60093. NDC: 53329-147-44

Product Quantity:
1,786 tubes

Reason for Recall:
Labeling: Not Elsewhere Classified; Product labeling contains the claim of 'Paraben Free' while the product does in fact contain parabens as part of the formulation/ ingredient list.

Recall Number:
D-0315-2024

Code Information:
Lot #s: 08926; 08926A Exp. 8/2025; 08928 Exp. 9/2025

Class II Drugs Event

Event ID:
93847

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/04/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
OMEZA LLC
1610 Northgate Blvd
Sarasota FL United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Omeza Lidocaine Lavage pain relief oil 10*2mL VIALS

Product Quantity:
4390 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0288-2024

Code Information:
Lots: 28622 2-1, Exp. 04/24/2024 286222-3, Exp. 1/25/2024 or 04/25/2024

Product Description:
Omeza Skin Protectant, Skin Protectant Gel 10*2mL Vials

Product Quantity:
1210 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0289-2024

Code Information:
Lot: 19123 4-1, Exp. 05/11/2024

Class II Drugs Event

Event ID:
93868

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
NATCO Pharma Limited
Pharma Division, Kothur Village
Rangareddy India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lansoprazole Delayed-Release Capsules USP, 15 mg, 14-count bottle, Manufactured by: Natco Pharma Limited Kothur- 509 228, India, Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ. 08816. NDC 16571-742-41

Product Quantity:
4260 bottles

Reason for Recall:
CGMP Deviations: Inadequate induction sealing on bottles, capsules were observed with bubbles on band seal, capsules with holes and spheres sticking to capsules. Also coding details were missing on one bottle.

Recall Number:
D-0318-2024

Code Information:
Lot # 411987 Exp: 05/2025

Class II Drugs Event

Event ID:
93918

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Febuxostat Tablets, 40 mg, 30 Tablets (3 x 10) per carton, Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-538-21, NDC Unit dose 60687-538-11

Product Quantity:
1,932 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0314-2024

Code Information:
Lot # 1015033, exp. 06/30/2025; 1016409, exp. 08/31/2025

Class III Drugs Event

Event ID:
93833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/06/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Glimepiride Tablets, USP 1mg, 100-count bottles, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam-532 409 INDIA, NDC: 55111-320-01

Product Quantity:
59,336 bottles

Reason for Recall:
Misprint on tablet

Recall Number:
D-0312-2024

Code Information:
Lot: T2303622; Exp. 06/2026 Lot: T2303626; Exp. 06/2026 Lot: T2303627; Exp. 06/2026 Lot: T2303628; Exp. 06/2026 Lot: T2303629; Exp. 06/2026

Product Description:
Glimepiride Tablets, USP 1mg, 500-count bottles, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam-532 409 INDIA, NDC: 55111-320-05

Product Quantity:
14,425 bottles

Reason for Recall:
Misprint on tablet

Recall Number:
D-0313-2024

Code Information:
Lot: T2303609; Exp. 06/2026 Lot: T2303610; Exp. 06/2026

Class III Drugs Event

Event ID:
93936

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
HydrALAZINE Hydrochloride Tablets, USP, 10 mg, 100-count (10 x 10) per unit dose carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 68084-447-01; NDC Unit Dose: 68084-447-11

Product Quantity:
2,850 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification (OOS) result in the repackaged product for Related Compounds (Impurities) at the 6-month time point.

Recall Number:
D-0320-2024

Code Information:
Lot #: 1012275, Exp 02/28/2025