Enforcement Report - Week of January 22, 2025

Class I Drugs Event

Event ID:
96003

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alcon Research LLC
6201 South Fwy
Fort Worth, TX 76134-2099
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Systane Lubricant Eye Drops, Ultra PF, Sterile, 25 Vials (0.7mL Each), Manufactured for: Alcon Laboratories, Inc. Forth Worth, TX 76134

Product Quantity:
55,960 25-count boxes

Reason for Recall:
Non-Sterility

Recall Number:
D-0200-2025

Code Information:
Lot 10101; Exp.09/30/2025

Class II Drugs Event

Event ID:
96033

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
glipiZIDE, Extended-Release Tablets, 2.5 mg, 30-count (3x10 blister cards) carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, Carton NDC: 60687-480-21, Unit Dose NDC: 60687-480-11

Product Quantity:
2,028 units (cartons of 30 individual unit doses)

Reason for Recall:
Failed Dissolution Specifications:

Recall Number:
D-0202-2025

Code Information:
Lot # 1012910, Exp Date: 04/30/2025

Class II Drugs Event

Event ID:
96036

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Cardura XL (doxazosin) extended release tablets 8 mg, 30-count bottle, Rx only, Distributed by Viatris Specialty LLC, Morgantown, WV 26505, NDC 58151-079-93

Product Quantity:
1,215/30 count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results observed for the impurity compound B during stability testing.

Recall Number:
D-0203-2025

Code Information:
Lot # 8181625, Exp 12/31/2025

Product Description:
Cardura XL (doxazosin) extended release tablets 4 mg, 30 -count bottle, Rx only, Distributed by Viatris Specialty LLC, Morgantown, WV 26505, NDC 58151-078-93

Product Quantity:
6,605/30 count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results observed for the impurity compound B during stability testing.

Recall Number:
D-0204-2025

Code Information:
Lot# 8182298, Exp 10/31/2025

Class II Drugs Event

Event ID:
96117

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Clobazam Tablets, 10 mg, packaged in 30 tablets per carton (3x10 blister cards each), Rx Only, Amneal Pharmaceuticals LLC, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC 60687-423-11

Product Quantity:
4640 units

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0201-2025

Code Information:
Lot #: 1018598, Exp. Date 10/31/2025

Class III Drugs Event

Event ID:
95944

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/10/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akron Pharma, Inc.
373 Us Highway 46 Ste 117
Fairfield, NJ 07004-2456
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Acetaminophen Extra Strength 500 mg, 100 Tablets per bottle, Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8022-01.

Product Quantity:
768 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0193-2025

Code Information:
Lot: KDT0224002A, Exp 09/30/2026

Product Description:
Acetaminophen Regular Strength, 325 mg, 100 Tablets per bottle, Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8024-01 .

Product Quantity:
6429 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0194-2025

Code Information:
Lot #: KDT0124001, Exp 08/31/2026

Product Description:
Acetaminophen, 325 mg Tablets, 100 Tablets per bottle, Akron Pharma, Manufactured for: Akron Pharma Inc., Fairfield, NJ 07034, NDC 71399-8014-01.

Product Quantity:
14825 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0195-2025

Code Information:
Lot #s: KDT0124004, KDT0124005, KDT0124006, Exp 08/31/2026

Product Description:
Acetaminophen Extra Strength 500 mg, 1000 Tablets per bottle, Akron Pharma, Manufactured for: Akron Pharma Inc., 373 US RT 46 W Building E, Suite 117, Fairfield, NJ 07034, NDC 71399-8022-02

Product Quantity:
1232 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0196-2025

Code Information:
Lot #s: KDT0224001B, Exp 08/31/2026; KDT0224002B, Exp 09/30/2026.

Product Description:
Diphenhydramine HCl 25 mg, 100 capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc., 373 RT US 46 W Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8028-1.

Product Quantity:
7198 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0197-2025

Code Information:
Lot: KDC0124001A Exp 09/30/2026.

Product Description:
Diphenhydramine HCl 25 mg, 1000 Capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc., 373 RT US 46 W Building E., Suite 117, Fairfield, NJ 07004, NDC 71399-8028-2.

Product Quantity:
456 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0198-2025

Code Information:
Lot: KDC0124002B Exp 09/30/2026

Product Description:
Diphenhydramine HCl 50 mg, 1000 capsules per bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc. 373 Route US 46, Building E, Suite 117, Fairfield, NJ 07004, NDC 71399-8026-02.

Product Quantity:
324 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Tablets/Capsules imprinted with wrong ID.

Recall Number:
D-0199-2025

Code Information:
Lot: KDC0224001B Exp 09/30/2026