Enforcement Report - Week of September 3, 2025

Class II Drugs Event

Event ID:
97361

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/22/2025

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

Associated Products

Product Description:
Sucralfate Tablets, USP 1 gram, 100 Tablets, (10x10), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217 NDC 60687-695-01 - Carton NDC [60687-695-11- Unit Dose]

Product Quantity:
26,992 blister packs

Reason for Recall:
CGMP Deviations: The recalling firm filed for Chapter 11 in September 2024. As a result, it cannot monitor the quality program and hence cannot assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess, rendering the products adulterated.

Recall Number:
D-0598-2025

Code Information:
Lot 1015038, Exp Date 07/31/2025, Lot 1015898, Exp Date 09/30/2025; Lot 1016873, Exp Date 10/31/2025 and Lot 1023398, Exp Date 07/31/2026.

Class II Drugs Event

Event ID:
97380

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cardinal Health Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091
United States

Distribution Pattern:
KS

Associated Products

Product Description:
Enoxaparin Sodium Injection, USP, 30 mg/0.3 mL, packaged in 0.3 mL prefilled syringes further packaged in bags of 5 prefilled syringes, Rx Only, Dist. by: Sandoz Inc., Princeton, NJ 08540, Outer package - NDC 55154-3543-5, Inner label - NDC 0781-3238-01

Product Quantity:
10 bags

Reason for Recall:
Correct Labeled Product Mispack: Bags labeled for Enoxaparin Sodium Injection, 80 mg/0.8 mL, contained Enoxaparin Sodium Injection, 30 mg/0.3 mL

Recall Number:
D-0597-2025

Code Information:
Outer package - NDC 55154-3543-5, Lot SAD08033AA Inner label - NDC 0781-3238-01, Lot SAF13211A

Class II Drugs Event

Event ID:
97385

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MEDLINE INDUSTRIES, LP - Northfield
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Medline Alcohol Prep Pads, 70% Isopropyl Alcohol, 100 Sterile 2-Ply Pads, Single Use Only, Large, www.medline.com, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA, 1-800-MEDLINE, NDC 53329-811-30.

Product Quantity:
6669874 swabs

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0600-2025

Code Information:
61224040057

Product Description:
CURAD Alcohol Prep Pads, Sterile, Medium, 2-Ply, Contents: 5 boxes per Carton, 30 Boxes per Case, Single Use Only, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093, USA, Made in India, www.curad.com, 1-800-633-5463, NDC 53329-827-30

Product Quantity:

1,639,996 pads

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0601-2025

Code Information:
61224050002

Product Description:
ReliOn, Sterile Alcohol Swabs, Skin Cleanser, 200 Swabs, Distributed by, Walmart, Inc., Bentonville, AR 72716 Walmart: 200 eaches per box, 24 boxes per case (4,800 eaches per case), NDC 49035-814-60.

Product Quantity:
3,456,000 pads

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0602-2025

Code Information:
61224070073

Product Description:
H-E-B, inControl, Sterile* Alcohol Pads, CONT. 100 PADS, Packaged in China with components from Taiwan, Elaborado Con Orgullo Y Cuidado PARA H-E-B, San Antonio, TX 78204, NDC 37808-809-09.

Product Quantity:
300000 pads

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0603-2025

Code Information:
61224080041

Product Description:
Good Neighbor Pharmacy, Alcohol Prep Pads, Distributed By AmeriSource Bergen, 1 West First Avenue, Conshohocken, PA 19428, Made in China: 100 eaches per box, 30 boxes per case, (3,000 eaches per case), NDC 46122-043-78.

Product Quantity:
66,000 pads

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0604-2025

Code Information:
61224070074

Product Description:
RITE AID PHARMACY, first aid alcohol prep pads, DISTRIBUTED BY: RITE AID. 200 NEWBERRY COMMONS, ETTERS, PA 17319, NDC 11822-5156-2.

Product Quantity:
984,000 pads

Reason for Recall:
Subpotent Drug- isopropyl alcohol levels fall below the labeled concentration.

Recall Number:
D-0605-2025

Code Information:
61224070083

Class II Drugs Event

Event ID:
97397

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/11/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company Inc.
1101 C Ave W
Seymour, IN 47274-3342
United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Lisdexamfetamine Dimesylate Capsules, 40 mg, 100-count bottles, Rx Only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC 0527-4664-37

Product Quantity:
8544 bottles

Reason for Recall:
Labeling: Label Mix-up. A bottle labeled as Lisdexamphetamine Dimesylate Capsules 40mg, contained Lisdexamphetamine Dimesylate Capsules 30mg.

Recall Number:
D-0599-2025

Code Information:
Lot #: 25280726A, Exp. Date 03/2027

Class II Drugs Event

Event ID:
97453

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield, IL 60015-4625
United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Acetaminophen Injection 1000 mg/100 mL (10 mg/mL), packaged in 100 mL Viaflo container, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, Made in Ireland, NDC 36000-306-60.

Product Quantity:
13,000 containers

Reason for Recall:
Discoloration

Recall Number:
D-0596-2025

Code Information:
Lot #: 24A27G66, Exp 12/31/2025