Enforcement Report - Week of July 9, 2025

Class I Drugs Event

Event ID:
97031

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/03/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Church & Dwight Inc
469 N Harrison St
Princeton, NJ 08540-3510
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
ZICAM COLD REMEDY MEDICATED NASAL SWABS, 20 Single-Use Swabs per carton, Distributed by Church & Dwight Co,. Inc., Ewing NJ. UPC 7 32216 30120 5

Product Quantity:
3,374,918 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Fungal contamination of nasal swabs.

Recall Number:
D-0504-2025

Code Information:
All lots.

Product Description:
ZICAM NASAL ALLCLEAR, 20 Single-Use Swabs per carton, Distributed by Church & Dwight Co,. Inc.., Ewing NJ. UPC 7 32216 30165 6

Product Quantity:
13,632 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Fungal contamination of nasal swabs.

Recall Number:
D-0505-2025

Code Information:
All Lots.

Product Description:
Orajel Baby, Cooling Swabs for Teething, Each Unit 0.007 fl oz (0.22 mL), NET 0.08 FL OZ (2.6 mL) TOTAL, 12 Single-Use Swabs per carton, Manufactured for Church & Dwight Co. Inc. Ewing. NJ 08328 USA. UPC CODE 3 10310 40000 2.

Product Quantity:
695,880 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Fungal contamination of infant oral swabs.

Recall Number:
D-0506-2025

Code Information:
All Lots.

Class I Drugs Event

Event ID:
97140

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton, NJ 08540-6604
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Cefazolin for Injection, USP, 1 gram per vial, Sterile, For Intramuscular or Intravenous Use, Rx Only, Manufactured by Sandoz GmbH for Sandoz Inc. Princeton, NJ 08540, NDC: 0781 3451-70 (vial), NDC: 0781-3451-96 (carton).

Product Quantity:
208,300 vials

Reason for Recall:
Labeling: Label Mix-Up; A complaint reported that vials of penicillin G potassium for Injection, USP, 20 million Unit vials were incorrectly included in a carton (25 vials per carton) of Cefazolin for Injection, USP 1 gram per vial product.

Recall Number:
N/A

Code Information:
Lot # PG4360, Exp. 11/30/2027

Product Description:
Buffered Penicillin G Potassium for Injection, USP 20,000,000 Units (20 million units), For IV use, Sterile, Rx Only, Manufactured in Austria by Sandoz GmbH for Sandoz Inc. Princeton, NJ 08540, NDC: 0781-6136-94.

Product Quantity:
unknown

Reason for Recall:
Labeling: Label Mix-Up; A complaint reported that vials of penicillin G potassium for Injection, USP, 20 million Unit vials were incorrectly included in a carton (25 vials per carton) of Cefazolin for Injection, USP 1 gram per vial product.

Recall Number:
N/A

Code Information:
Lot # PG4360, Exp. 11/30/2027

Class II Drugs Event

Event ID:
96996

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/02/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/30/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Tailstorm Health INC
24416 N 19th Ave Ste 200
Phoenix, AZ 85085-1400
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
LIDOcaine HCl Injection, USP, 10mg/mL, 1% (100 mg/10mL), 10 mL Sterile Single Dose Vial, Rx Only, For Infiltration & Nerve Block, Including Caudal & Epidural Use, Preservative-Free, For Office Use Only, Compounded Drug by: Medivant Healthcare, 158 S Kyrene Rd., Chandler, AZ, 85226, NDC 81483-0000-0.

Product Quantity:
29,700 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0498-2025

Code Information:
Lot #s: 2502004, Exp. 2/18/27; 2503003, Exp. 3/19/27

Product Description:
BUPIVAcaine HCL Sterile injection, USP w/EPINEPHRINE 1:200,000, 50 mg/10mL, 0.5%, (5mg/mL), 10 mL Sterile Single-Dose Vial, Rx Only, For Nerve Block, Caudal & Epidural Anesthesia Only, Warning: Contains Sulfites, For Office Use Only, Compounded Drug by: Medivant Healthcare, 158 S. Kyrene Rd., Chandler, AZ, 85226, NDC 81483-0036-0.

Product Quantity:
975 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0499-2025

Code Information:
Lot #s: 2502005, Exp. 2/20/26; 2502006, Exp 2/23/2026

Product Description:
KETAmine Hydrochloride Injection, USP, 50 mg/5mL (10 mg/mL), For IM Use or Slow IV Use, 5 mL Sterile Single-Dose Vial, Rx Only, For Office Use Only, Compounded Durg by: Medivant Healthcare, 158 S. Kyrene Rd. Chandler, AZ 85226, NDC 81483-0006-0.

Product Quantity:
23,200 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0500-2025

Code Information:
Lot #s: 2502008, Exp. 2/27/2027; 2503001, Exp. 3/4/2027.

Product Description:
KETAmine Hydrochloride Injection, USP, 500mg/5mL, (10mg/mL), For IM or Slow IV Use, 5mL Sterile Multi-Dose Vial, Rx Only, For Office Use Only, Compounded Drug by: Medivant Healthcare, 158 S. Kyrene, Rd. Chandler, AZ 85226, NDC 81483-0007-2.

Product Quantity:
14,725 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0501-2025

Code Information:
Lot: 2502009, Exp. 3/2/2026

Product Description:
LIDOcaine HCL Sterile Injection, USP, 100mg/10mL, 1%, (10mg/mL), w/EPINEPHRINE 1:100,000, For Infiltration & Nerve Block, Including Caudal & Epidural Use, 10 mL Sterile Single-Dose Vial, For Office Use Only, Compounded Drug by: Medivant Healthcare, 158 S. Kyrene, Rd. Chandler, AZ 85226, NDC 81483-0037-0.

Product Quantity:
2825 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0502-2025

Code Information:
Lot #s: 2503004, Exp. 3/23/2026; 2503005, Exp. 3/25/2026

Product Description:
LIDOcaine HCL Sterile Injection, USP, 20 mg/mL, 2%, (200 mg/10 mL), For Infiltration & Nerve Block, Including Caudal & Epidural Use, Preservative Free, 10mL Sterile Single-Dose Vial, Rx Only, Medivant Healthcare, 158 S. Kyrene Rd., Chandler, AZ, 85226, NDC 81483-0001-0.

Product Quantity:
4875 vials

Reason for Recall:
Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.

Recall Number:
D-0503-2025

Code Information:
Lot #: 2504003, Exp. 04/03/2027

Class II Drugs Event

Event ID:
97087

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/19/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/03/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group LLC
7000 Cardinal Pl

Dublin, OH 43017-1091
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Gabapentin Capsules, USP, 100 mg, 100 capsules (10x10), blister pack cartons, Rx only, Packaged and Distributed by: MAJOR PHARMACEUTICALS, Indianapolis, IN, 46268 USA, NDC 0904-6665-61

Product Quantity:
23,232 cartons

Reason for Recall:
Defective container; blister packaging inadequately sealed.

Recall Number:
D-0507-2025

Code Information:
Lot# M05205, Exp Date 10/2026

Product Description:
Gabapentin Capsules, USP, 100 mg, 10 capsules (10x1) per bag, Rx only, Packaged and Distributed by: MAJOR PHARMACEUTICALS, Indianapolis, IN, 46268 USA, Distributed by Cardinal Health, Dublin, OH 43017, NDC 55154-3363-0

Product Quantity:
3,527 bags

Reason for Recall:
Defective container; blister packaging inadequately sealed.

Recall Number:
D-0508-2025

Code Information:
Lot# M05205A and M05205B, Exp Date 10/2026.

Class II Drugs Event

Event ID:
97131

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/08/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Granules Pharmaceuticals Inc.
3701 Concorde Pkwy
Chantilly, VA 20151-1126
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Metoprolol Succinate Extended-Release Tablets, USP, 25 mg, Packaged in a) 100-count bottle, NDC 70010-780-01; b) 500-count bottle, NDC

70010-780-05; Rx only, Manufactured by: Granules India Limited, Hyderadab-500 081, India, Manufactured for: Granules Pharmaceuticals Inc., Chantilly, VA 20151,

Product Quantity:
27,648 100-count Bottles; 5,376 500-count Bottles

Reason for Recall:
Failed Dissolution Specifications: Product failed to meet dissolution acceptance criteria in the stability studies at the 6th month (25¿C/60% RH) long-term.

Recall Number:
D-0510-2025

Code Information:
Lot # a)1400008A, Exp Date: 12/31/2025; b) 1400008B, Exp Date: 12/31/2025