

# Enforcement Report - New Recalls Added Since Last Weekly Enforcement Report (Updated Daily)

## 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 #: 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 #: 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

## Not Yet Classified Drugs Event

**Event ID:**

97031

**Status:**

Ongoing

**Recall Initiation Date:**

06/06/2025

**Center Classification Date:**

N/A

**Recalling Firm:**

Church & Dwight Inc  
469 N Harrison St

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Press Release

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:**  
N/A

**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:**  
N/A

**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:**  
N/A

**Code Information:**  
All Lots.

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## Not Yet Classified Drugs Event

**Event ID:**  
97131

**Status:**  
Ongoing

**Recall Initiation Date:**  
06/24/2025

**Center Classification Date:**  
N/A

**Product Type:**  
Drugs

**Date Terminated:**  
N/A

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**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, Hyderabad-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:**

N/A

**Code Information:**

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