Enforcement Report - Week of December 24, 2025

Class II Drugs Event

Event ID:
98059

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/26/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/15/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo, CA 93012-8601
United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Baclofen Tablets USP, 10 mg, 1000-count bottles, Rx only, Marketed by: GSMS, Incorporated, CA 93012 USA. NDC 51407-973-10

Product Quantity:
2472 HDPE Bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0235-2026

Code Information:
Lot GS065762

Class II Drugs Event

Event ID:
98080

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novocol Pharmaceutical of Canada, Inc.
25 Wolseley Crt
Cambridge
Canada

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
2% Xylocaine DENTAL with Epinephrine 1:100,000 (Lidocaine HCl and Epinephrine Injection USP), packaged in a carton containing 50 single-dose cartridges, 1.7 mL each, Rx only, Manufactured for Dentsply Pharmaceutical, York, PA 17404, by Novocol Pharmaceutical of Canada, Inc., NDC 66312-176-16.

Product Quantity:
18,789 cartons- 50 cartridges /carton

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0228-2026

Code Information:
Lot: D05337B, expires: 06-30-2027

Product Description:
Lidocaine HCl 2% and Epinephrine 1:100,000 (Lidocaine HCl and Epinephrine Injection USP), packaged in a carton containing 50 single-dose Cartridges, 1.7 ml each, Rx only, Manufactured for Patterson Dental Supply, Inc., 1031 Mendota Heights Road, Saint Paul, MN55120, Manufactured by: Novocol Pharmaceutical of Canada, Inc., NDC 50227-1030-5.

Product Quantity:
12,033 cartons

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0229-2026

Code Information:
Lot: D05362A, expires: 07-31-2027

Product Description:
3% Polocaine DENTAL, Mepivacaine Hydrochloride 3% (30mg/mL) (Mepivacaine HCl Injection, USP), packaged in a carton containing 50 single-dose Cartridges, 1.7 ml each, Rx only, Manufactured for Dentsply Pharmaceutical, York, PA 17404, by Novocol Pharmaceutical of Canada, Inc., NDC 66312-441-16.

Product Quantity:
5,825

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0230-2026

Code Information:
Lot: D05159C, expires: 07-31-2027

Product Description:
darby dental supply, MEPIVACAINE, Mepivacaine HCl 3% (30mg/mL) Injection, [Mepivacaine HCl Injection, USP], packaged in a carton containing 50 single-dose Cartridges, 1.7 mL each, Rx only, Manufactured by Novocol Pharmaceutical of Canada, Inc., NDC 66467-9760-5.

Product Quantity:
5,520 Cartons

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0231-2026

Code Information:
Lot: D05159G, expires: 07-31-2027

Product Description:
Benco dental Graham CHEMICAL CO., Mepivacaine HCl 3% (30 mg/mL) Injection, [Mepivacaine HCl Injection, USP], packaged in a carton

containing 50 single-dose Cartridges, 1.7 mL each, Rx only, Distributed by Benco Dental 295 Center Point Blvd, Pittston, PA 18640, Manufactured by Novocol Pharmaceutical of Canada, Inc., NDC 66975-406-51.

Product Quantity:
N/A

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0232-2026

Code Information:
Lot: D05159H, expires: 07-31-2027

Product Description:
Cook-Walte, Carbocaine 3% (30 mg/mL), (mepivacaine hydrochloride Injection, USP), packaged in a carton containing 50 Single-Dose Cartridges, 1.7 mL, Rx only, Manufactured by Novocol Pharmaceutical of Canada, Inc., NDC 0362-0753-05.

Product Quantity:
40 cartons

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0233-2026

Code Information:
Lot: D05159I, expires: 07-31-2027

Product Description:
OraVerse, (Phentolamine Mesylate) Injection, 0.4 mg/1.7mL, packaged in a carton containing 10 cartridges, 0.4 mg/1.7mL, Rx only, Made in Canada by Novocol Pharmaceutical of Canada, Inc., Distributed by Septodont, Inc., Louisville, Co, 80027, NDC 0362-0101-10

Product Quantity:
1,636 cartons

Reason for Recall:
Defective container: cracked/broken cartridges

Recall Number:
D-0234-2026

Code Information:
Lot: D05004E, expires: 04-30-2027

Class II Drugs Event

Event ID:
98104

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMA /TARO
3 Skyline Dr
Hawthorne, NY 10532-2174
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ciclopirox Shampoo, 1%, 120 mL, Rx only, Mfg by: Taro Pharmaceuticals Inc., Ontario, Canada; Dist. by: Taro Pharmaceuticals USA, Inc., NY 10532. NDC 51672-1351-08

Product Quantity:
17,664 units

Reason for Recall:
Failed Impurity/Degradation specifications: OOS results obtained at the 18-month timepoint

Recall Number:
D-0240-2026

Code Information:
Lot #: AD37059, AD37060, AD37061, AD37062, AD37065, AD37066, AD37067, AD37068, expires: 1/31/2026.

Class II Drugs Event

Event ID:
98141

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim, CA 92807-1801
United States

Distribution Pattern:
Natinowide in the USA

Associated Products

Product Description:
Ondansetron ODT Tablets, USP 4mg, 1x10 unit dose tablets, Mfg: Glenmark Pharmaceuticals Limited, Repackaged by Preferred Pharmaceuticals NDC 68788-8666-01

Product Quantity:
575 1x10 Foil Blister Packs

Reason for Recall:
Defective container: Preferred Pharmaceuticals received a letter from the manufacturer Glenmark, that the blister packs are not fully sealed and tablets falling out. Preferred Pharmaceuticals purchased the finished product and repackaged the product for sale.

Recall Number:
D-0239-2026

Code Information:
Lot: J1325J, I1725P, EXP Date: 4/30/2027.

Class III Drugs Event

Event ID:
98063

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/26/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/15/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SOMERSET THERAPEUTICS LLC
300 Franklin Square Dr
Somerset, NJ 08873-4187
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Cisatracurium Besylate Injection USP, 10 mg/5 mL* (2mg/mL), 10 x 5 mL Single-dose Vials per Carton, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Hollywood, FL 33024, Made in India, Single-dose 5 mL vial NDC 70069-141-01; 10x5 mL single dose vial per Carton NDC 70069-141-10.

Product Quantity:
52,340 5mL vials

Reason for Recall:
Subpotent product:out of specification assay results observed during long term stability testing.

Recall Number:
D-0236-2026

Code Information:
Lot#: A240438, Exp Date 1/31/26, A250125, Exp Date 8/31/26

Product Description:
Cisatracurium Besylate Injection USP, 200mg/20mL*(10mg/mL), 10 x 20 mL Single-dose Vials per Carton, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Hollywood, FL 33024, Made in India, Single dose 20mL vial NDC 70069-151-01; 10 x 20 Single dose vials per Carton, NDC 70069-151-10.

Product Quantity:
28,660 20mL vials

Reason for Recall:
Subpotent product:out of specification assay results observed during long term stability testing.

Recall Number:
D-0237-2026

Code Information:
Lot #: A250020, Exp Date 06/30/2026

Product Description:
Cisatracurium Besylate Injection USP, 20 mg/10 mL*,(2 mg/mL), 10 x 10 mL Multiple-dose Vials per carton, Rx Only, Manufactured for: Somerset Therapeutics, LLC, Hollywood, FL 33024, Made in India, 10mL Multiple-dose vial, NDC 70069-161-01; 10x10mL Multiple-dose vials per Carton, NDC 70069-161-01.

Product Quantity:
71,310 10mL vials

Reason for Recall:
Subpotent product:out of specification assay results observed during long term stability testing.

Recall Number:
D-0238-2026

Code Information:
Lot#: A250043, EXP Date 06/30/2026