

# Enforcement Report - Week of April 22, 2026

## Class II Drugs Event

**Event ID:**

98596

**Status:**

Ongoing

**Recall Initiation Date:**

03/17/2026

**Center Classification Date:**

04/14/2026

**Recalling Firm:**

Nephron SC, LLC  
4500 12th Street Ext  
West Columbia, SC 29172-3025  
United States

**Distribution Pattern:**

Nationwide within the United States

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

N/A



## Associated Products

**Product Description:**

Albuterol Sulfate Inhalation Solution, 0.5%, 25 mg/5 mL (5 mg/mL\*), 30x5 mL Sterile Unit-Dose Vials, Rx only, nephron 503B Outsourcing facility, 4600 12th Street Extension, West Columbia, SC 29172, NDC 69374-330-05.

**Product Quantity:**

146,280 vials

**Reason for Recall:**

Labelling: Illegible label

**Recall Number:**

D-0479-2026

**Code Information:**

Lot AB6001, exp date 1/15/2027

## Class II Drugs Event

**Event ID:**

98646

**Status:**

Ongoing

**Recall Initiation Date:**

03/06/2026

**Center Classification Date:**

04/13/2026

**Recalling Firm:**

PAYLESS COMPOUNDERS, LLC  
8505 Sw Creekside Pl Ste 110  
Beaverton, OR 97008-7128  
United States

**Distribution Pattern:**

OR

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Semaglutide-Glycine-Cyanocobalamin Injectable, 2.5 mg, 5 mg, 1 MG/ML, 0.5 mL vials, Rx only, Northwest Compounders, Beaverton, OR

**Product Quantity:**

91 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0471-2026

**Code Information:**

Lot Number 01-27-2026@14S.5



## Class II Drugs Event

**Event ID:**

98648

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

03/20/2026

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/10/2026

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

Letter

**Recalling Firm:**

Xiamen Kang Zhongyuan Biotechnology Co., Ltd.

No. 2018 2 Jietou Road

Xiamen

China

**Distribution Pattern:**

US Nationwide.

## Associated Products

**Product Description:**

exchange select, Menthol -Cough Suppressant Oral Anesthetic, Honey Lemon Flavor Cough Drops, 30-count bag, Manufactured for Your Military Exchanges By: Medical Group Care, LLC., 1035 Collier Center Way, STE 5, Naples, FL, Made in China, NDC 83698-580-30, UPC: 614299398870.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0456-2026

**Code Information:**

Lot # 20241030, Exp Date: 10/30/2026

**Product Description:**

exchange select, Menthol- Cough Suppressant Oral Anesthetic, Cough Drops, Menthol Flavor, 30-count bag, Manufactured for Your Military Exchanges By: Medical Group Care, LLC, 1035 Collier Center Way, STE 5, Naples, FL, Made in China, NDC: 83698-581-30, UPC: 614299398887.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the

manufacturing facility that may bear on product quality.

**Recall Number:**

D-0457-2026

**Code Information:**

Lot # 20241030, Exp Date: 10/30/2026

**Product Description:**

caring mill, Menthol Cough Suppressant Oral Anesthetic, Cough Drops, Cherry, 90-count bag, Distributed by: FSA Store Inc., 5473 Blair Rd, Suite 100, PMB 24308, Dallas TX 75231, Made in China, NDC: 83698-421-90, UPC: 810025928407.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0458-2026

**Code Information:**

Lot # 20241030, Exp Date: 10/30/2026

**Product Description:**

Discount Drug Mart Food Market, Cough Drops, Menthol- Cough Suppressant Anesthetic, Honey Lemon, 30-count bag, Distributed By: Drug Mart-Food Fair, Medina, Ohio, 44256, Made in China, NDC: 83698-150-30, UPC: 093351037092.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0459-2026

**Code Information:**

Lot # 20241030, Exp Date: 10/30/2026

**Product Description:**

Discount Drug Mart Food Market, Cough Drops, Menthol -Cough Suppressant Anesthetic, 30-count bag, Distributed By: Drug Mart-Food Fair, Medina, Ohio 44256, Made in China, NDC: 83698-102-30, UPC: 093351037085.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0460-2026

**Code Information:**

Lot # 20241030, Exp Date: 10/30/2026

**Product Description:**

MGC Health, Menthol- Cough Suppressant, Oral Anesthetic, Cough Drops, Sugar Free, Honey Lemon, 25-count bag, Distributed By: Medical Group Care, LLC, 1035 Collier Center Way, STE 5, Naples, FL 34110, NDC: 83698-125-25, UPC: 383173000085

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0461-2026

**Code Information:**

Lot# 20240524, Exp Date: 05/24/2026; Lot# 20240720, Exp Date: 07/20/2026; Lot# 20240730, Exp Date: 07/30/2026.

**Product Description:**

MGC Health, Menthol- Cough Suppressant, Oral Anesthetic, Cough Drops, Honey Lemon, 30-count bag, Distributed By: Medical Group Care, LLC, 1035 Collier Center Way, STE 5, Naples, FL 34110, NDC: 83698-114-30, UPC: 383173000047.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0462-2026

**Code Information:**

Lot# 20240524, Exp Date: 05/24/2026.

**Product Description:**

MGC Health, Menthol- Cough Suppressant, Oral Anesthetic, Cough Drops, Honey Lemon, 80-count bag, Distributed By: Medical Group Care, LLC, 1035 Collier Center Way, STE 5, Naples, FL 34110, NDC: 83698-114-80, UPC: 383173000030.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0463-2026

**Code Information:**

Lot# 20240730, Exp Date: 07/30/2026.

**Product Description:**

QC Quality Choice, Menthol- Cough Suppressant Oral Anesthetic, Cough Drops, Sugar Free, Black Cherry Flavor, 25-count bag, Distributed By: CDMA, Inc., Novi MI 48375, Made in China, NDC: 83698-616-25, UPC: 635515993372.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0464-2026

**Code Information:**

Lot# 20240720, Exp Date: 07/20/2026.

**Product Description:**

QC Quality Choice, Menthol- Cough Suppressant Oral Anesthetic, Cough Drops, Cherry Flavor, 30-count bag, Distributed By: CDMA, Inc., Novi MI 48375, Made in China, NDC: 83698-616-25, UPC: 635515993372.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0465-2026

**Code Information:**

Lot # 20240524, Exp Date: 05/24/2026; Lot # 20240720, Exp Date: 07/20/2026.

**Product Description:**

QC Quality Choice, Menthol-Cough Suppressant Oral Anesthetic, Cough Drops, Sugar Free, Honey Lemon Flavor, 25-count bag, Distributed By: CDMA, Inc., Novi, MI 48375, Made in China, NDC: 83698-616-25, UPC: 635515993372.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0466-2026

**Code Information:**

Lot # 20240720, Exp Date: 07/20/2026, Lot # 20241030, Exp Date: 10/30/2026.

**Product Description:**

QC Quality Choice, Pectin Oral Demulcent, Throat Soothing Drops, Creamy Strawberry Flavor, 30-count bag, Distributed By: CDMA, Inc., Novi, MI 48375, Made in China, NDC: 83698-625-30, UPC: 635515999398.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0467-2026

**Code Information:**

Lot # 20240720, Exp Date: 07/20/2026.

**Product Description:**

QC Quality Choice, Menthol-Cough Suppressant Oral Anesthetic, Cough Drops, Honey Lemon Flavor, 30-count bag, Distributed By: CDMA Inc., Novi, MI 48375, Made in China, NDC: 83698-617-30, UPC: 63551598673.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0468-2026

**Code Information:**

Lot # 20240720, Exp Date: 07/20/2026.

**Product Description:**

QC Quality Choice, Menthol-Cough Suppressant Oral Anesthetic, Cough Drops, Menthol Flavor, 30-count bag, Distributed By: CDMA Inc., Novi, MI 48375, Made in China, NDC: 83698-675-30, UPC: 635515986718.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality.

**Recall Number:**

D-0469-2026

**Code Information:**

Lot # 20240720, Exp Date: 07/20/2026; Lot # 20240524, Exp Date: 05/24/2026.




**Product Description:**

QC Quality Choice, Menthol-Cough Suppressant Oral Anesthetic, Cough Drops, Vanilla Honey Flavor, 30-count bag, Distributed By: CDMA Inc., Novi, MI 48375, Made in China, NDC: 83698-620-30, UPC: 635515999411.

**Product Quantity:**

N/A

**Reason for Recall:**

This recall is being initiated following FDA's recommendation based on certain observations noted during an August 15, 2025, inspection of the manufacturing facility that may bear on product quality. 

**Recall Number:**

D-0470-2026

**Code Information:**

Lot # 20240720, Exp Date: 07/20/2026.

## Class II Drugs Event

**Event ID:**

98670

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

03/16/2026

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/10/2026

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

Letter

**Recalling Firm:**

Cipla USA, Inc.  
10 Independence Blvd  
Warren, NJ 07059-2730  
United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Cinacalcet Hydrochloride Tablets, 30 mg, 30 Tablets per bottle, Rx Only, Manufactured by: Cipla Ltd., MIDC, Patalganga, India; Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-410-02

**Product Quantity:**

113,336 bottles

**Reason for Recall:**

CGMP Deviations; presence N-Nitroso Cinacalcet above the acceptable daily intake limit

**Recall Number:**

D-0449-2026

**Code Information:**

Lot, expiry: Lot 4PB0526, 4PB0527, 4PB0528, exp September-2026; Lot 5PB0173, exp January-2027

**Product Description:**

Cinacalcet Hydrochloride Tablets, 60 mg, 30 Tablets per bottle, Rx Only, Manufactured by: Cipla Ltd., MIDC, Patalganga, India; Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-411-02

**Product Quantity:**

96,096 bottles

**Reason for Recall:**

CGMP Deviations; presence N-Nitroso Cinacalcet above the acceptable daily intake limit

**Recall Number:**

D-0450-2026

**Code Information:**

Lot, expiry: 4PB0215, 4PB0216, exp March-2026; 4PB0515, 4PB0516, exp September-2026; 4PB0517, exp September-2026; 5PB0167, exp January-2027

**Product Description:**

Cinacalcet Hydrochloride Tablets, 90 mg, 30 Tablets per bottle, Rx Only, Manufactured by: Cipla Ltd., MIDC, Patalganga, India; Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-412-02

**Product Quantity:**

63,192 bottles

**Reason for Recall:**

CGMP Deviations; presence N-Nitroso Cinacalcet above the acceptable daily intake limit

**Recall Number:**

D-0451-2026

**Code Information:**

Lot, expiry: 4PB0224, exp March-2026; 4PB0505, 4PB0506, 4PB0507, exp September-2026; 5PB0564, exp April-2027

## Class II Drugs Event

**Event ID:**

98672

**Status:**

Ongoing

**Recall Initiation Date:**

03/24/2026

**Center Classification Date:**

04/17/2026

**Recalling Firm:**

The Harvard Drug Group LLC  
7000 Cardinal PI  
Dublin, OH 43017-1091  
United States

**Distribution Pattern:**

US Nationwide.

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Memantine Hydrochloride Extended-Release, Capsules, 7 mg, 100 Capsules (10 x 10 blister packs), Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268, NDC 0904-6734-61

**Product Quantity:**

N/A

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0485-2026

**Code Information:**

Lot # N02425, Exp Date: 05/31/2027.

## Class II Drugs Event

**Event ID:**

98677

**Product Type:**

Drugs

**Status:**  
Ongoing

**Date Terminated:**  
N/A

**Recall Initiation Date:**  
03/25/2026

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

**Center Classification Date:**  
04/13/2026

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

**Recalling Firm:**  
SUN PHARMACEUTICAL INDUSTRIES INC  
2 Independence Way  
Princeton, NJ 08540-6620  
United States

**Distribution Pattern:**  
Nationwide in the USA.



## Associated Products

<p><b>Product Description:</b> Fluocinonide, USP, 0.05% Cream, 15g tube, Rx only, Mfd by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1, Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1386-1</p> <p><b>Product Quantity:</b> 24,672 15 g tubes</p> <p><b>Reason for Recall:</b> Failed Viscosity Specifications: Out of Specification results, above the specification limit, in viscosity, noted during stability testing.</p> <p><b>Recall Number:</b> D-0475-2026</p> <p><b>Code Information:</b> Lot# AD76252, Exp Date: 6/30/2026.</p>
<p><b>Product Description:</b> Fluocinonide, USP, 0.05% Cream, 30g tube, Rx only, Mfd by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1, Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1386-2.</p> <p><b>Product Quantity:</b> 41,712 30g tubes</p> <p><b>Reason for Recall:</b> Failed Viscosity Specifications: Out of Specification results, above the specification limit, in viscosity, noted during stability testing.</p> <p><b>Recall Number:</b> D-0476-2026</p> <p><b>Code Information:</b> Lot# AD76251, Exp Date: 6/30/2026.</p>
<p><b>Product Description:</b> Fluocinonide, USP, 0.05% Cream, 60g tube, Rx only, Mfd by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1, Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1386-3.</p> <p><b>Product Quantity:</b> 2,640 60g tubes</p> <p><b>Reason for Recall:</b> Failed Viscosity Specifications: Out of Specification results, above the specification limit, in viscosity, noted during stability testing.</p> <p><b>Recall Number:</b> D-0477-2026</p> <p><b>Code Information:</b> Lot# AD76250, Exp Date: 6/30/2026.</p>

## Class II Drugs Event

**Event ID:**  
98683

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**  
N/A

**Recall Initiation Date:**  
03/03/2026

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

**Center Classification Date:**  
04/10/2026

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



**Recalling Firm:**

Owen Biosciences Inc.  
7053 Revenue Dr  
Baton Rouge, LA 70809-4918  
United States

**Distribution Pattern:**

U.S. Nationwide

## Associated Products

**Product Description:**

FHF Farmhouse Fresh, Midnight Clearing, NIGHT LOTION, 2.5% BENZOYL PEROXIDE ACNE TREATMENT, OTC a) 0.5 fl. oz./15ml; and b) 1 fl. oz./30ml tubes; Made in the USA for FarmHouse Fresh, 8797 CR 858 McKinney, Texas

**Product Quantity:**

7,975 tubes

**Reason for Recall:**

Chemical contamination: Presence of benzene

**Recall Number:**

D-0452-2026

**Code Information:**

Lot #2595500, Exp.10/2/2026 Lot #2549700, Exp.6/12/2026 Lot #2638200, Exp.4/30/2027

**Product Description:**

HydroPeptide CLEAR ALLIANCE SERUM, 2.5% BENZOYL PEROXIDE, a) 1 FL OZ/30ml; b) 2 FL OZ/60ml spray bottle; DIST BY HYDROPEPTIDE LLC, ISSAQUAH, WA 98027

**Product Quantity:**

9,850 bottles

**Reason for Recall:**

Chemical contamination: Presence of benzene

**Recall Number:**

D-0453-2026

**Code Information:**

Lot# 2518800, Exp.: 4/30/2027 Lot# 2518900, Exp.: 4/1/2027

**Product Description:**

SLMD BP Acne Spot Treatment, 10% Benzoyl Peroxide, 0.5 fl. oz - 15 mL bottles, Sandra Lee MD, Distributed by Skin PS Brands, Culver City, CA90232.

**Product Quantity:**

2269 bottles

**Reason for Recall:**

Chemical contamination: Presence of benzene

**Recall Number:**

D-0454-2026

**Code Information:**

Lot# 2567200, Exp.8/1/26 Lot# 2691600, Exp.10/30/2027

**Product Description:**

SLMD Benzoyl Peroxide Acne Lotion, Benzoyl Peroxide 2.5%, a) 0.7 fl. oz - 21 mL and b) 1.5 fl. oz. - 44mL bottles, SANDRA LEE MD., Distributed by Skin PS Brands, Culver City, CA 90232.

**Product Quantity:**

2,500 bottles

**Reason for Recall:**

Chemical contamination: Presence of benzene

**Recall Number:**

D-0455-2026

**Code Information:**

Lot# 2691700, Exp.10/31/2027 Lot# 2691800, Exp. 11/4/2027



## Class II Drugs Event

**Event ID:**

98690

**Status:**

Ongoing

**Recall Initiation Date:**

04/01/2026

**Center Classification Date:**

04/14/2026

**Recalling Firm:**

International Medication Systems Ltd.  
1886 Santa Anita Ave  
South El Monte, CA 91733-3414  
United States

**Distribution Pattern:**

U.S. Nationwide

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

EPINEPHRINE Injection, USP, 1 mg/10mL (0.1 mg/mL), Rx only, INTERNATIONAL MEDICATION SYSTEMS, LIMITED, So. EL Monte, CA 91733, An Amphastar Pharmaceutical Company, NDC 76329-3318-1

**Product Quantity:**

81,520 units

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0483-2026

**Code Information:**

Lot Number: EA038A5, Expiration Date: 08/2026.

## Class II Drugs Event

**Event ID:**

98705

**Status:**

Ongoing

**Recall Initiation Date:**

04/01/2026

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**  
04/22/2026

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

**Recalling Firm:**

Island Kinetics, Inc. d.b.a. CoValence Laboratories  
460 S Benson Ln Ste 1-3  
Chandler, AZ 85224-5663  
United States

**Distribution Pattern:**

U.S. Nationwide



## Associated Products

**Product Description:**

Blemish Spot Treatment (Salicylic Acid) 1%, .5 fl oz (15 ml) bottles, Skin Script, Chandler, AZ 85226, UPC 6 10563 13873 9.

**Product Quantity:**

28,163 bottles

**Reason for Recall:**

Failed Stability Specifications

**Recall Number:**

D-0487-2026

**Code Information:**

Lot#: 4228D2, 4229D1, Exp.: 07/31/2026 Lot#: 5147D2, Exp.: 04/30/2027

## Class III Drugs Event

**Event ID:**

98624

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

03/18/2026

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/14/2026

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

Letter

**Recalling Firm:**

Island Kinetics, Inc. d.b.a. CoValence Laboratories  
460 S Benson Ln Ste 1-3  
Chandler, AZ 85224-5663  
United States

**Distribution Pattern:**

U.S. Nationwide

## Associated Products

**Product Description:**

Remedy Gel, hydrocortisone 1%, 30 mL/ 1 fl oz per bottle, Distributed By: glo Skin Beauty, Denver, CO 80216. NDC 66915-531-12; 66915-531-13

**Product Quantity:**

1060 bottles

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0480-2026

**Code Information:**

Lot 4155D2, 4155D3; Exp. 05/15/2026

**Product Description:**

Skin Rehab, Calming Skin Gel, Hydrocortisone Balm, hydrocortisone 1%, .53oz net wt. (15.3g) per bottle, Distributed By: A.C.E. Inc., DFW Intl. Airport, Texas 75261, www.RHONDAALLISON.COM. NDC 66915-531-04

**Product Quantity:**

2895 bottles

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0481-2026

**Code Information:**

Lot 4212D2; Exp. 07/03/2026

**Product Description:**

Essential Calming Skin Gel, hydrocortisone 1%, 120mL/4oz net wt. (113g) per jar, Distributed By: A.C.E. Inc., DFW Intl. Airport, Texas 75261, www.RHONDAALLISON.COM, NDC 66915-531-05

**Product Quantity:**

299 bottles

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0482-2026

**Code Information:**

Lot 4212D4; Exp. 07/31/2026

## Class III Drugs Event

**Event ID:**

98689

**Status:**

Ongoing

**Recall Initiation Date:**

03/31/2026

**Center Classification Date:**

04/22/2026

**Recalling Firm:**

Avantor Performance Materials LLC  
7001 Martin Luther King Jr Blvd  
Paris, KY 40361-2147  
United States

**Distribution Pattern:**

Nationwide in the USA, Belgium and France

**Product Type:**

Drugs

**Date Terminated:**

N/A

**Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Magnesium Chloride, 6-Hydrate, Crystal, 500G per bottle, Bulk active pharmaceutical ingredient (API), Avantor Performance Materials, LLC, 100 Matsonford Road, Suite 200, Radnor, PA 19087, NDC 10106-2448-1

**Product Quantity:**

36 bottles

**Reason for Recall:**

Subpotent drug

**Recall Number:**

D-0488-2026

**Code Information:**

Lot 23G3161005, Exp 9/21/2027

**Not Yet Classified Drugs Event****Event ID:**

98724

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

04/02/2026

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

N/A

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

N/A

**Recalling Firm:**

Huons Co., Ltd.  
100 Bio-Valley-Ro  
Jecheon  
Korea (the Republic of)

**Distribution Pattern:**

Nationwide.

**Associated Products****Product Description:**

Lidocaine HCl injection, USP, 1% 50mg/5mL (10 mg/mL), 5 mL Single Dose Vials (NDC 63739-170-13), packaged in 10 count cartons (NDC 63739-170-24) and 25 count cartons (NDC 63739-170-27), Rx only, Distributed by: McKesson Corporation, dba Sky Packaging, Manufactured by: Huons Co, Ltd, Chungcheongbuk-do, Korea

**Product Quantity:**

33,599,925 ampules and 23,658,125 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

N/A

**Code Information:**

All lots within expiry

**Product Description:**

Bupivacaine Hydrochloride in 8.25 Dextrose Injection, USP, 0.75% (15 mg/2 mL) (7.5 mg/mL), Rx only, Manufactured by: Houns Co., Ltd, 100, Bio valley, Je-cheor-Si, Chungcheongbuk-dc, Korea NDC 73293-0002-2 50 x 2 Single-dose ampules, NDC 73293-0002-1 - 2 mL ampule - Single Use Ampule 73293-0002-2 - 50 mL ampule in 1 package

**Product Quantity:**

3,260,170 ampules

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

N/A

**Code Information:**

All lots within expiry

**Product Description:**

0.9% Sodium Chloride Injection, USP, 10 mL Ampules, Rx only, Single Dose, Preservative Free, Manufactured for: Spectra Medical Devices, LLC, Wilmington, MA, 01887, By: Houns Co., Ltd, Jecheon, Korea, 27159, NDC 65282-1510-1.

**Product Quantity:**

7,120,750 ampules

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

N/A

**Code Information:**

All lots within expiry



## Not Yet Classified Drugs Event

**Event ID:**

98736

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

04/08/2026

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

N/A

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

E-Mail

**Recalling Firm:**

Apotex Corp.  
2400 N Commerce Pkwy Ste 400  
Weston, FL 33326-3253  
United States

**Distribution Pattern:**

Within U.S

## Associated Products

**Product Description:**

Desmopressin Nasal Spray, USP, 10 mcg/0.1 mL, 5 mL bottle (50 doses), Rx only, Mfg by: Apotek inc., Toronto, Ontario, Canada, M9L 1T9, Mfg for: Apotek Corp., Weston, FL 33326, NDC 60505-0815-0

**Product Quantity:**

N/A

**Reason for Recall:**

Defective container: defect in a batch of bottle caps, specifically involving dislodged or missing cap liners.

**Recall Number:**

N/A

**Code Information:**

Lot: VM4231, Expires: 06/2027.