

# Enforcement Report - Week of May 28, 2025

## Class II Drugs Event

**Event ID:**

96797

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

04/24/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/19/2025

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

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

**Recalling Firm:**

KENIL HEALTHCARE PRIVATE LIMITED  
Plot 319 Village Acharasan, Ankhol-Vamaj Road  
Ta. Kadi, District Mehsana  
India

**Distribution Pattern:**

DE and NC

## Associated Products

**Product Description:**

Artridon Glucosamine (menthol 2% and Methyl Salicylate 15% - Topical Analgesic), for arthritis joint pain relief, 5 oz (142g) Tube, Dist by/por: Pharmadel LLC, New Castle, DE, 19720, Made in India, NDC 55758-030-05, UPC 8 10096 77151 3.

**Product Quantity:**

9,984 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0421-2025

**Code Information:**

Lot SP25A, Exp Date: 09/30/2026

**Product Description:**

CURA HONGOS, Antifungal, 1% Clotrimazole, Topical Lotion, 0.76 fl oz (22.5 mL) Bottle, Dist by/por: Pharmadel LLC, New Castle, DE 19720, Made in India, NDC 55758-34-01, UPC 8 10096 77170 4.

**Product Quantity:**

10,128 Bottles

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0422-2025

**Code Information:**

Lot SP31A, Exp Date: 09/30/2026

**Product Description:**

CURA HONGOS, Antifungal Cream, Clotrimazole 1%, Net Wt/ Peso Neto 2 oz (56.7g) Tube, Distributed by: Pharmadel LLC, New Castle, DE 19720, Made in India, UPC 8 997110 011052.

**Product Quantity:**

10,788 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0423-2025

**Code Information:**

Lot SP23A, Exp Date: 03/31/2026

**Product Description:**

Kingskin, SacaCallos, 17% Salicylic acid, 0.5 fl oz (14.8mL) Bottle, Dist. by: Pharmadel LLC, New Castle, DE 19720, Made in India, NDC 55758-423-15, UPC 8 10096 77163 6.

**Product Quantity:**

9,000 Bottles

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0424-2025

**Code Information:**

Lot SP28A, Exp Date: 09/30/2026

**Product Description:**

KOFAL Original, Penetrating Pain Relieving Ointment (methyl salicylate 12% - Topical Analgesic), 4 oz (113 g) Jar, Distributed by: Pharmadel LLC, Georgetown, DE 199747, NDC 55758-106-04, UPC 8 9971100128 0.

**Product Quantity:**

16,248 Jars

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0425-2025

**Code Information:**

Lost SP21A, Exp Date: 03/31/2026

**Product Description:**

KOFAL, Athletes, Penetrating Pain Relief, External Analgesic Ointment (methyl salicylate 10.5% - External Analgesic), 2 oz (60 g) Jar, Distributed by: Pharmadel LLC, New Castle, DE 19720, NDC 55758-109-02, UPC 8 99711 00101 3.

**Product Quantity:**

11,808 Jars

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0426-2025

**Code Information:**

Lot SP30A, Exp Date: 09/30/2026

**Product Description:**

Optim V, Anti-Itch Cream, Benzocaine 20% & Resorcinol 3% - External analgesic, Net Wt. Peso Neto 1 oz (28g) Tube, Distributed by: Pharmadel LLC, New Castle, DE 19720, Made in India, NDC 55758-300-01, UPC 8 59424 00420 6.

**Product Quantity:**

6,372 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0427-2025

**Code Information:**

Lot SP24A, Exp: 09/30/2026

**Product Description:**

Rapidol Maximum Strength, Hydrocortisone 1% Anti-Itch Cream, NET WT 2 oz (60g) Tube, Distributed by: Pharmadel LLC, New Castle, DE, 19720, NDC 55758-420-02, UPC 8 10096 77158 2.

**Product Quantity:**

10,000 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0428-2025

**Code Information:**

Lot SP26A, Exp: 09/30/2026

**Product Description:**

Rapidol, Triple Antibiotic First Aid Ointment, Bacitracin Zinc/ Neomycin Sulfate/ Polymyxin B Sulfate, Net Wt 2 oz (56g) Tube, Distributed by: Pharmadel LLC, New Castle, DE, 19720, Made in India, NDC 55758-440-02, UPC 8 10096 77162 9.

**Product Quantity:**

9,336 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0429-2025

**Code Information:**

Lot SP27A, Exp: 09/30/2026

**Product Description:**

Cinnafresh anticavity gel toothpaste, sodium fluoride 0.22%, Bold Cinnamon Flavor, NET WT. 0.85 OZ (24 grams) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-133-01

**Product Quantity:**

383,904 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0430-2025

**Code Information:**

Lot B0011, B0012, Exp Date: 05/31/2026; Lot B0070, B0074, Exp Date: 08/31/2026; Lot B0075, B0077, B0078, B0079, B0080, B0081, B0082, B0083, B0084, B0085, Exp Date: 09/30/2026

**Product Description:**

Maximum Security Anticavity Gel Toothpaste, Sodium Fluoride 0.22%, Fresh Mint Flavor, Net Wt 0.6 OZ (17 g) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-132-02

**Product Quantity:**

391,680 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0431-2025

**Code Information:**

Lot B0009, B0017, Exp Date: 05/31/2026; Lot B0018, B0019, B0036, B0037, B0038, Exp Date: 06/30/2026; Lot B0049, Exp Date: 07/31/2026; B0063, Exp Date: 08/31/2026

**Product Description:**

Maximum Security, Anticavity Gel Toothpaste, Sodium Fluoride 0.22%, Fresh Mint Flavor, NET WT 0.85 oz (24 g) Tube, Made in India, Dist. by Bob Barker Co. Inc. Fuquay-Varnia, NC 27526, NDC 53247-132-03

**Product Quantity:**

615, 600 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0432-2025

**Code Information:**

Lot B0008, B0009, B0017, Exp Date: 05/31/2026; Lot B0042, B0043, B0044, Exp Date: 06/30/2026; Lot B0049, B0050, B0051, B0054, B0058, B0059, Exp Date: 07/31/2026; Lot B0061, B0062, B0063, B0064, B0065, B0068, B0069, Exp Date: 08/31/2026

**Product Description:**

Maximum Security, Anticavity Gel Toothpaste, Sodium Fluoride 0.22%, Fresh Mint Flavor, NET WT 0.15 OZ (4.25 g) Sachets, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-132-01

**Product Quantity:**

1,559,000 Sachets

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0433-2025

**Code Information:**

Lot B0010, B0017, Exp Date: 05/31/2026; Lot B0028, B0029, B0030, Exp Date: 06/30/2026; Lot B0052, Exp Date: 07/31/2026; Lot B0091, Exp Date: 09/30/2026

**Product Description:**

Maximum Security, Anticavity Gel Toothpaste, Sodium Fluoride 0.22%, Fresh Mint Flavor, NET WT 1.5 OZ (43 g) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-132-04

**Product Quantity:**

216,720 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0434-2025

**Code Information:**

Lot B0013, Exp Date: 05/31/2026; Lot B0018, Exp Date: 06/30/2026; Lot B0053, B0054, Exp Date: 07/31/2026; Lot B0090, B0091, B0092, B0093, B0094, B0095, B0096, B0097, B0098, B0099, B0100, B0101, Exp Date: 09/30/2026

**Product Description:**

Nature Mint, Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 4.6 OZ (130 grams) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-06

**Product Quantity:**

19,500 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0435-2025

**Code Information:**

Lot B0027, B0031, Exp Date: 06/30/2026; Lot B0032, Exp Date: 07/31/2026

**Product Description:**

Nature Mint, Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 0.6 OZ (17g) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-02

**Product Quantity:**

498,960 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0436-2025

**Code Information:**

Lot B0015, B0016, Exp Date: 05/31/2026; Lot B0020, B0021, B0022, Exp Date: 06/30/2026; Lot B0056, B0057, Exp Date: 07/31/2026; Lot B0108, B0109, B0110, Exp Date: 09/30/2026

**Product Description:**

Nature Mint, Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 6.4 OZ (181 grams) Box, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-07

**Product Quantity:**

4,176 boxes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0437-2025

**Code Information:**

Lot B0067, Exp Date: 08/31/2026

**Product Description:**

Nature Mint Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 0.85 OZ (24 grams) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-03

**Product Quantity:**

616,160 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0438-2025

**Code Information:**

Lot B0014, B0015, B0022, B0023, Exp Date: 05/31/2026; Lot B0024, B0025, B0026, B0027, B0033, B0034, B0035, B0039, B0040, B0041, B0045, Exp Date: 06/30/2026; Lot B0046, Exp Date: 07/31/2026

**Product Description:**

Nature Mint Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 1.5 OZ (43 grams) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-04

**Product Quantity:**

150,768 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0439-2025

**Code Information:**

Lot B0004, Exp Date: 05/31/2026; B0060, Exp Date: 07/31/2026; Lot B0067, B0071, B0072, Exp Date: 08/31/2026; Lot B0107, B0108, Exp Date: 09/30/2026

**Product Description:**

Nature Mint, Anticavity Fluoride Toothpaste, Sodium monofluorophosphate 0.76%, NET WT 2.75 OZ (78g) Tube, Made in India, Dist. by Bob Barker Co. Inc., Fuquay-Varina, NC 27526, NDC 53247-131-05

**Product Quantity:**

160,848 Tubes

**Reason for Recall:**

CGMP Deviations

**Recall Number:**

D-0440-2025

**Code Information:**

Lot B0032, B0047, B0048, B0055, B0056, Exp Date: 07/31/2026; B0102, B0103, B0104, B0105, B0106, B0107, Exp Date: 09/30/2026

## Class II Drugs Event

**Event ID:**

96847

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

05/09/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/21/2025

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

E-Mail

**Recalling Firm:**

KVK Tech, Inc.

110 Terry Dr

Newtown, PA 18940-3427

United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

Indomethacin Extended-Release Capsules USP, 75 mg, 100-count bottle, Rx only, Mfd. By: KVK-Tech, Inc., Newtown, PA, 18940, Made in USA, NDC 10702-016-01.

**Product Quantity:**

9107 bottles

**Reason for Recall:**

cGMP deviations

**Recall Number:**

D-0445-2025

**Code Information:**

Lot#: 18400A, Exp 7/31/2027

**Product Description:**

Phentermine Hydrochloride Capsules, USP 30mg, 100-count bottle, Rx Only, Mfd. By: KVK-Tech, Inc., Newtown, PA, 18940, Made in USA, NDC 10702-028-01.

**Product Quantity:**

9680 bottles

**Reason for Recall:**

cGMP deviations

**Recall Number:**

D-0446-2025

**Code Information:**

Lot#: 18350A, 18351A, Exp 6/30/2027

## Class II Drugs Event

**Event ID:**

96857

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

05/14/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/21/2025

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

Letter

**Recalling Firm:**

AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
Wilmington, DE 19897-0001  
United States

**Distribution Pattern:**

USA Nationwide

## Associated Products

**Product Description:**

Airsupra (albuterol and budesonide) inhalation aerosol, 90 mcg/80 mcg per inhalation, packaged in a) 120-inhalation canister (NDC 0310-9080-12) b) 28-inhalation canister (NDC 0310-9080-28), Rx only, Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850, By: AstraZeneca Dunkerque Production (AZDP), Dunkerque, France, Product of France, .

**Product Quantity:**

a) 807,837 canisters; b) 235,698 canisters

**Reason for Recall:**

Defective delivery system

**Recall Number:**

D-0444-2025

**Code Information:**

Lot#: a) 6270044C00, 6270040D00, 6270034E00, Exp Date 10/2026; 6270053C00, 6270045C00, 6270047C00, 6270056C00, 6270052C00, 6270063E00 Exp 11/30/2026; 6270064C00, 6270071D00, 6270075D00, 6270075F00 Exp Date 12/31/2026; 6270107C00, Exp Date 9/30/2027; b) Lot 6270019E00, Exp Date 7/31/2025; 6270021D00, Exp 8/31/2025; 6270095C00, Exp 2/28/2026

## Class II Drugs Event

**Event ID:**

96860

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

05/13/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/20/2025

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

Letter

**Recalling Firm:**

Zydus Pharmaceuticals (USA) Inc  
73 Route 31 N  
Pennington, NJ 08534-3601  
United States

**Distribution Pattern:**

Nationwide -in the USA

## Associated Products

**Product Description:**

Esomeprazole Magnesium for Delayed-Release Oral Suspension, 40 mg, 30-count Single-Dose Packets per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-849-94

**Product Quantity:**

30,674 30 sachets/carton

**Reason for Recall:**

Failed Impurities/Degradation Specifications: Out-of-Specification test results obtained for any individual unknown degradation product during Related Compounds testing during long term stability.

**Recall Number:**

D-0442-2025

**Code Information:**

Lot # M311638, Exp 07/2025, M400374, Exp 10/2025, M402496, Exp 02/2026, M407998, Exp 05/2026, M502247, Exp 11/2026, M414770, M414512, Exp 09/2026.

**Product Description:**

Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg, 30-count single dose packets per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-848-94

**Product Quantity:**

22,152 30 sachets/carton

**Reason for Recall:**

Failed Impurities/Degradation Specifications: Out-of-Specification test results obtained for any individual unknown degradation product during Related Compounds testing during long term stability.

**Recall Number:**

D-0443-2025

**Code Information:**

Lot #:M402147, Exp 10/2025; M311637, Exp 07/2025; M402495, Exp 02/2026; M407997, Exp 05/2026; M502246, Exp11/2026.

## Class II Drugs Event

**Event ID:**

96879

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

N/A

**Recall Initiation Date:**

05/15/2025

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/20/2025

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

Letter

**Recalling Firm:**

CareFusion 213, LLC  
1550 Northwestern Dr  
El Paso, TX 79912-8000  
United States

**Distribution Pattern:**

Nationwide in the U.S.

## Associated Products

**Product Description:**

BD Chloraprep Clear, 2% x/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Patient Preoperative Skin Preparation, Sterile Solution, Applicator is sterile if package is intact, Flammable, External Use Only, 1 mL Applicator per pouch, 60 Applicators per inner carton, CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., Made in the USA, Catalog Number 930480, NDC 54365-400-31.

**Product Quantity:**

385,200 applicators

**Reason for Recall:**

Lack of Assurance of Sterility: The affected product may exhibit an open seal on the packaging of the applicator.



**Recall Number:**

D-0441-2025

**Code Information:**

Lot #s: 3354127 and 3350974, Exp Date: 12/31/2026