Enforcement Report - Week of May 13, 2026

Class I Drugs Event

Event ID:
98795

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/28/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/18/2026

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
B BRAUN MEDICAL INC
861 Marcon Blvd
Allentown, PA 18109-9577
United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Lactated Ringer's Injection USP, 1000 mL container, Rx only, B. Braun Medical, Inc., Bethlehem, PA 18018-3524 USA, NDC 0264-7750-07.

Product Quantity:
95,412 containers

Reason for Recall:
Presence of Particulate Matter.

Recall Number:
D-0540-2026

Code Information:
Lot #:J4P756, J4S843, Exp 5/31/2027

Class II Drugs Event

Event ID:
98781

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/20/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Acella Pharmaceuticals, LLC
1880 Mcfarland Pkwy Ste 110
Alpharetta, GA 30005-1795
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
NAPROXEN ORAL SUSPENSION, USP, 125 mg/5mL, Rx only, 16fl oz (473 mL) bottles, Distributed by: Acella Pharmaceuticals, LLC, Alpharetta, GA 30005, Made in Canada NDC 42192-619-16

Product Quantity:
6,336 bottles

Reason for Recall:
Chemical contamination; presence of lead and lithium above specification

Recall Number:
D-0523-2026

Code Information:
Lot: 23F02, Expires: 05/2026; 25A37, Expires: 01/2028.

Class II Drugs Event

Event ID:
98785

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/29/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/04/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ajanta Pharma Ltd.
B-4/5/6 MIDC Industrial Area Paithan
Aurangabad
India

Distribution Pattern:
Nationwide within U.S

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, 30 mg, Rx Only, a) 90 Capsules, NDC 27241-098-09, b) 30 capsules, NDC 27241-098-03, c) 1000 Capsules, NDC 27241-098-10, Marketed by: Ajanta Pharma USA Inc., Bridgewater, NJ 08807, Made in India

Product Quantity:
312,894 packs

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-Duloxetine impurity above FDA recommended limit of 0.83 ppm, identified at the 12-month and 18-month long-term stability intervals.

Recall Number:
D-0514-2026

Code Information:
Lot#: a) PA10774, Exp. May 2026; b) PA10794, PA12174, Exp. Jun 2026; c) PA10804, Exp. Jun-26.

Product Description:
Duloxetine Delayed-Release Capsules, 60 mg, Rx Only, 30 capsules, Marketed by: Ajanta Pharma USA Inc., Bridgewater, NJ 08807, Made in India, NDC 27241-099-03

Product Quantity:
77,376 packs.

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-Duloxetine impurity above FDA recommended limit of 0.83 ppm, identified at the 12-month and 18-month long-term stability intervals.

Recall Number:
D-0515-2026

Code Information:
Lot#: PA07434, Exp. May 2026.

Product Description:
Duloxetine Delayed-Release Capsules, 20 mg, Rx Only, 60 capsules, Marketed by: Ajanta Pharma USA Inc., Bridgewater, NJ 08807, Made in India, NDC 27241-097-06.

Product Quantity:
117,168 packs

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-Duloxetine impurity above FDA recommended limit of 0.83 ppm, identified at the 12-month and 18-month long-term stability intervals.

Recall Number:
D-0516-2026

Code Information:
Lot#: PA10734, Exp. Jun 2026.

Class II Drugs Event

Event ID:
98790

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/22/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2026

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 USA

Associated Products

Product Description:
BD PurPrep, Povidone-iodine 8.3% w/w (0.83% available iodine) with isopropyl alcohol 72.5% w/w Sterile Solution, 25x26mL Applicators per carton. Carefusion 213 LLC, El Paso, TX 79912, NDC 54365-014-42.

Product Quantity:
N/A

Reason for Recall:
Lack of assurance of Sterility: potential product contamination

Recall Number:
D-0517-2026

Code Information:
Lot# 4258309, 4260329, 4256875, Exp. Date, 08-31-2026; 4296453, 4317319, 4290654, Exp. Date 09-30-2026; 4322449, 4323861, 4318679, Exp Date 10-31- Exp.

Product Description:
BD PurPrep, Povidone-iodine 8.3% w/w (0.83% available iodine) with isopropyl alcohol 72.5% w/w Sterile Solution, 0.36 fl. oz. (10.5 mL) x 25 applicators per box. Carefusion 213, LLC, El Paso, TX 79912, subsidary of Becton Dickinson and Co. NDC 54365-014-41

Product Quantity:
N/A

Reason for Recall:
Lack of assurance of Sterility: potential product contamination

Recall Number:
D-0518-2026

Code Information:
Lots# 4263873, Exp. Date 08-31-2026, 4320590, Exp. Date 09-30-2026, 4320591, Exp. Date 10-31-2026.

Class II Drugs Event

Event ID:
98794

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/23/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
JB Chemicals and Pharmaceuticals Ltd
Neelam Centre A Wing A B Wing 4th Floor; Hind Cycle Road
Mumbai
India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Enalapril Maleate Tablets, USP, 20 mg, 1,000-count bottle, Rx only, Manufactured by: Unique Pharmaceutical Laboratories (A Div. of J.B. Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India, Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816, NDC 64980-688-10.

Product Quantity:
675 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:Out of specification result occurred in Organic Impurities Test

Recall Number:
D-0520-2026

Code Information:
Lot #: GEH25023, Expires: 6/30/2027

Class II Drugs Event

Event ID:
98803

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/21/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc.
200 Connell Dr Ste 4200
Berkeley Heights, NJ 07922-2805
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 60mg, Rx Only, 90-count bottle, Mfr. by Towa Pharmaceutical Eurpoe S.L., Martorelles, (Barcelona), Spain, Dist. by. Breckenridge Pharmaceutical, Inc., Berkely Heights, NJ 07922, NDC 51991-748-90.

Product Quantity:
165,761 90-count bottles

Reason for Recall:
CGMP Deviations; presence of N-nitroso-duloxetine impurity above the FDA recommended limit

Recall Number:
D-0522-2026

Code Information:
Lot: 241069C, Exp 05/31/2027

Class II Drugs Event

Event ID:
98810

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/24/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/05/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Octreotide Acetate for Injectable Suspension, for gluteal intramuscular use, 30 mg, In Single-Dose kits containing: 8-mL vial of 30 mg strength, a pre-filled syringe containing 2 mL of diluent, one vial adapter, and one sterile 1¿ 19-gauge safety injection needle, Rx only, Manufactured in Greece BY: Pharmathen International S.A, Rodopi, 69300 Greece, Manufactured For: TEVA Pharmaceuticals, Parsippany, NJ 07054. NDC Kit Carton: 0480-9262-08; Vial Label: 0480-9260-01; Tray Label: 0480-9262-08; Diluent Label: 0480-9263-21.

Product Quantity:
2,200 kits

Reason for Recall:
Lack of Assurance of Sterility: Quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection at the contract manufacturer.

Recall Number:
D-0519-2026

Code Information:
Lot: 45011002, Exp. 03/31/2027

Class II Drugs Event

Event ID:
98829

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/06/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/04/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 920
Waltham, MA 02451-1521
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
DELFLEX, Dextrose Peritoneal Dialysis Solution with attached stay-safe Exchange Set for Intraperitoneal Dialysis Only, 1.5% DEX. LM/LC, 2L 5PK, Part Number 054-20221, Fresenius Medical Care North America, 920 Winter Street, Waltham, MA 02451.

Product Quantity:
37,215 bags

Reason for Recall:
Lack of Assurance of Sterility: Potential leaks from perforations in bags.

Recall Number:
D-0512-2026

Code Information:
Lot #: 25CU02007, 25CU02008, 25CU02009

Product Description:
DELFLEX, Dextrose Peritoneal Dialysis Solution with attached stay-safe Exchange Set for Intraperitoneal Dialysis Only, 2.5% DEX. LM/LC, 2L 5PK, Part Number 054-20222, Fresenius Medical Care North America, 920 Winter Street, Waltham, MA 02451.

Product Quantity:
43,225 bags

Reason for Recall:
Lack of Assurance of Sterility: Potential leaks from perforations in bags.

Recall Number:
D-0513-2026

Code Information:
Lots 25CU02002, 25CU02011, 25CU02012, 25CU02013

Class II Drugs Event

Event ID:
98831

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/07/2026

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Central Admixture Pharmacy Services, Inc (CAPS) Los Angeles
13128 Imperial Hwy
Santa Fe Springs, CA 90670-4817
United States

Distribution Pattern:
CA

Associated Products

Product Description:
TPN bag (patient specific), Rx# 11-4909703-0-1, Compound Volume 1660 mL per bag, Rx only, Single Dose Injection, Refrigerated Injection, Central Admixture Pharmacy Services, Los Angeles, 13128 Imperial Hwy, Santa Fe Spr., CA 90670

Product Quantity:
1 bag

Reason for Recall:
Incorrect Product Formulation: product did not contain insulin as listed in the label.

Recall Number:
D-0524-2026

Code Information:
Lot #: 11-4909703-0-1, Exp 12/28/2025

Class III Drugs Event

Event ID:
98728

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/13/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/01/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Unichem Pharmaceuticals USA Inc.
1 Tower Center Blvd Ste 2200
East Brunswick, NJ 08816-1145
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
busPIRone Hydrochloride Tablets, USP, 5 mg, 500-count bottle, Rx Only, Manufactured by Unichem Laboratories LTD., Ind, Area, Meerut Road, Ghazibad - 201 003, India Manufactured for: Unichem Pharmaceuticals (USA), Inc. East Brunswick, NJ 08816, NDC 29300-244-05.

Product Quantity:
10,875 Bottles

Reason for Recall:
Subpotent drug

Recall Number:
D-0511-2026

Code Information:
Lot: ZBUL25001, Exp 12/31/2027