

Enforcement Report - Week of May 27, 2026

Class I Drugs Event

Event ID:

98788

Status:

Ongoing

Recall Initiation Date:

04/24/2026

Center Classification Date:

05/29/2026

Recalling Firm:

Wisconsin Pharmacal Company
 N168w22223 Main St
 Jackson, WI 53037
 United States

Distribution Pattern:

USA Nationwide and Bahamas

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter



Associated Products

Product Description:

MG217 Multi-Symptom Treatment Cream & Skin Protectant (colloidal oatmeal 2%), NET WT 6 oz (170 g), Manufactured by: Pharmacal 1 Pharmacal Way, P.O. Box 198, Jackson, WI 53037.

Product Quantity:

690 tubes

Reason for Recall:

Microbial Contamination of Non-Sterile Products: confirmed presence of Staphylococcus Aureus.

Recall Number:

D-0553-2026

Code Information:

Lot #: 1024088, Exp 11/30/2026

Class II Drugs Event

Event ID:

98809

Status:

Ongoing

Recall Initiation Date:

04/24/2026

Center Classification Date:

05/19/2026

Recalling Firm:

Lupin Pharmaceuticals Inc.
 5801 Pelican Bay Blvd Ste 500
 Naples, FL 34108-2734
 United States

Distribution Pattern:

Nationwide within U.S

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Liraglutide Injection, 18 mg/3 mL (6 mg/mL), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Naples, FL 34108, Manufactured by: Lupin Limited, Nagpur 441108, INDIA, a) 2 Pens- NDC 70748-346-02; b) 3 Pens - NDC 70748-346-03.

Product Quantity:

217,621 pen injectors

Reason for Recall:

Presence of particulate matter: a white thread-like structure in the cartridge

Recall Number:

D-0541-2026

Code Information:

Lots: a) WB00097, WB00094, WB00088, Expires: Jul. 2027; WB00103, Expires: Oct. 2027; WC00016, Expires: Dec. 2027; b) WB00098, WB00092, WB00093, Expires: Jul. 2027; WB00104, WB00106, WB00105, Expires: Oct. 2027.

Class II Drugs Event

Event ID:

98870

Product Type:

Drugs


Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

04/29/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/20/2026

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 within the U.S

Associated Products

Product Description:

Erythromycin Tablets, USP, 250 mg, 30 tablets per bottle, Rx only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534; a) 30 count bottles (NDC 70710-1047-3); b) 100 count bottles (NDC 70710-1047-1).

Product Quantity:

23,880 bottles

Reason for Recall:

CGMP Deviations; presence of N-Nitroso-Desmethyl-Erythromycin above the recommended acceptable intake limit

Recall Number:

D-0544-2026

Code Information:

Lots: a) M411146, Expires: 08/2026; M502098, M502097, Expires: 01/2027; b) M411145, Expires: 08/2026.

Product Description:

Erythromycin Tablets, USP, 500 mg, 30 tablets per bottle, Rx only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534; (NDC 70710-1048-3).

Product Quantity:

10,992 bottles

Reason for Recall:

CGMP Deviations; presence of N-Nitroso-Desmethyl-Erythromycin above the recommended acceptable intake limit

Recall Number:

D-0545-2026

Code Information:

Lots: a) M411147, Expires: 08/2026; M502100, M502099, Expires: 01/2027.

Class II Drugs Event

Event ID:

98885

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

04/30/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/18/2026

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Safecor Health, LLC
 4060 Business Park Dr Ste B
 Columbus, OH 43204-5047
 United States

Distribution Pattern:

TX only



Associated Products

Product Description:

Atomoxetine Capsules HCL, 10 mg Capsules in unit dose foil strip, strips are packed in cartons of 100, Rx Only, Pkg by: Safecor, Columbus, OH 43204. NDC: 64380-474-01

Product Quantity:

149 capsules

Reason for Recall:

Labeling: Label Mix-Up: Atomoxetine HCl 25mg Capsule incorrectly labeled as Atomoxetine HCl 10mg Capsule.

Recall Number:

D-0538-2026

Code Information:

Lot #: 25530722

Class II Drugs Event

Event ID:

98899

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/01/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/21/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Safecor Health, LLC
 4060 Business Park Dr Ste B

Columbus, OH 43204-5047
United States

Distribution Pattern:
OH

Associated Products

Product Description:

Vitamin B-Complex, Vitamin C & Folic Acid Dietary Supplement Oral Liquid, Contains: Folic Acid 799 mcg/5mL, Delivers 5 mL per oral syringe, (Nephronex), Mfg By: LLORENS; Pkg by: Safecor, Columbus, OH. NDC 54859-0516-08

Product Quantity:

520 syringes

Reason for Recall:

Presence of a Foreign Substance; black particles observed in liquid

Recall Number:

D-0549-2026

Code Information:

Lot, expiry: Lots 26110722, 26110743, exp 9/8/2026; Lot 26111218, exp 9/9/2026



Class II Drugs Event

Event ID:

98910

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/11/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/19/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Haleon US Holdings LLC
184 Liberty Corner Rd Ste 200
Warren, NJ 07059-6870
United States

Distribution Pattern:

U.S. Nationwide.

Associated Products

Product Description:

Gas-X, Simethicone 125 mg/ ANTIGAS, 120 SoftGels, Distributed by: Haleon, Warren, NJ 07059, UPC: 3 00674 35041 9.

Product Quantity:

285,330 blister cards

Reason for Recall:

Labeling: Not Elsewhere Classified- Incomplete inactive ingredient information on the carton labeling.

Recall Number:

D-0542-2026

Code Information:

Lot: KB5Y, Expires: 04/2028; MP4B, Expires: 05/2028; SS4F, Expires: 09/2028.

Class II Drugs Event

Event ID:

98915

Product Type:

Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/08/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
UCB Biosciences Inc.
1950 Lake Park Dr SE
Smyrna, GA 30080-7648
United States

Distribution Pattern:
US Nationwide.

Associated Products


Product Description:
cimzia (certolizumab pegol), 2x200mg/mL PREFILLED SYRINGES (2 single-dose), Rx ONLY, Manufactured by: UCB Inc., Smyrna, GA 30080, a) NDC 50474-710-79, b) Professional sample, NDC 50474-710-80; c) 3 cartons, STARTER KIT, NDC 50474-710-81.

Product Quantity:
141,708 cartons

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0546-2026

Code Information:
Lot: CVZFW, Exp.:2026-JUL-04; CVZYG, Exp.: 2026-AUG-19; CWSYT, Exp.: 2026-OCT-22; CWDZY, Exp.:2026-NOV-20; CWTSD, Exp.:2026-DEC-11; CVTFK, Exp.:2026-JUL-04; CVTSN, Exp.: 2026-AUG-19; CWVGP, Exp.:2026-DEC-11; CVWXT, CVWXV, CVWXW, Exp.:2026-JUL-04; CWHFF, Exp.: 2026-OCT-22; CWNDS, Exp.: 2026-DEC-11.



Class II Drugs Event

Event ID:
98947

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/12/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ANI Pharmaceuticals, Inc.
210 W Main St
Baudette, MN 56623-2467
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Estradiol Gel, 0.1%, 0.25 mg, 0.25 g per packet, 30 packets per carton, Rx only, Distributed by: ANI Pharmaceuticals, Inc., Baudette, MN 56623. NDC 70954-531-20

Product Quantity:

3964 Cartons

Reason for Recall:

Defective Container; packets were found to be either empty or partially full.

Recall Number:

D-0543-2026

Code Information:

Lot M251109, exp Nov 2027

Class II Drugs Event

Event ID:

98991

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/12/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/21/2026

Initial Firm Notification of Consignee or Public:

N/A

**Recalling Firm:**

IntegraDose Compounding Services LLC
3650 Victoria St N Ste 900
Shoreview, MN 55126-2906
United States

Distribution Pattern:

Nationwide.

Associated Products

Product Description:

fentaNYL Citrate, Sterile CADD for Injection, 2,2500 mcg/50mL in Sterile Water, IntegraDose Compounding Services LLC, 3650 Victorie St N, Suite 900, Shoreview, MN, NDC 71139-6030-1.

Product Quantity:

376 cassettes

Reason for Recall:

Subpotent Drug

Recall Number:

D-0548-2026

Code Information:

Lot#: 20260310FEN-1, Exp. Date: 09/06/2026

Class III Drugs Event

Event ID:

98791

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

04/24/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/18/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Lannett Company Inc.

1101 C Ave W
Seymour, IN 47274-3342
United States

Distribution Pattern:

USA Nationwide

Associated Products**Product Description:**

Primidone Tablets USP, 250mg, 100-count bottle, Rx only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136, NDC 0527-1231-01.

Product Quantity:

44865 bottles

Reason for Recall:

Cross contamination with other products: API contaminated with trace amounts of Acemetacin API.

Recall Number:

D-0533-2026

Code Information:

Lot#: 25283038A, Exp 1/31/2028; 25283564A, 25283565A, Exp 3/31/2028; 25285712A Exp 08/31/2028; 25284105A, Exp 4/30/2028; 25284874A, 25284875A, Exp 08/31/2028.

**Class III Drugs Event****Event ID:**

98856

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

04/27/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/18/2026

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:

USA Nationwide

Associated Products**Product Description:**

Primidone Tablets, USP, 50 mg, 50-count bottle, RX only, Manufactured by: Lannett Company, Inc., Marketed by: GSMS, Incorporated, Camarillo, CA 93012. NDC 51407-637-05

Product Quantity:

8,526 bottles

Reason for Recall:

Cross contamination with other products: API contaminated with trace amounts of Acemetacin API.

Recall Number:

D-0534-2026

Code Information:

Lot#: GS066750, GS067084, GS067710, GS067873, Exp 3/31/2028; GS068339, GS068897, Exp 8/31/2028

Product Description:

Primidone Tablets, USP, 250 mg, 100-count bottle, RX only, Manufactured by: Lannett Company, Inc., Marketed by: GSMS, Incorporated, Camarillo,

CA 93012, NDC 51407-638-01

Product Quantity:

1,620 bottles

Reason for Recall:

Cross contamination with other products: API contaminated with trace amounts of Acemetacin API.

Recall Number:

D-0535-2026

Code Information:

Lot #: GS067909, Exp 4/30/2028; GS068646, Exp 8/31/2026

Class III Drugs Event

Event ID:

98883

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/04/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/18/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Sagent Pharmaceuticals
 1515 E Woodfield Rd Ste 1100
 Schaumburg, IL 60173-6067
 United States

Distribution Pattern:

Nationwide within the United States



Associated Products

Product Description:

Busulfan Injection, 60 mg per 10 mL (6 mg per mL), 8x10 mL Single-Dose Vials, Rx only, Mfd. for Sagent Pharmaceuticals, Schaumburg, IL 60195, Made in Canada, NDC 25021-241-10.

Product Quantity:

Lot 656412: 6,200 vials. Lot 659646: 3,328 vials.

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0539-2026

Code Information:

Lot #: 656412, Exp. Date 08/31/2026; 659646, Exp. Date 03/31/2027.

Class III Drugs Event

Event ID:

98884

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/01/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/18/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Primidone Tablets, USP, 250 mg, 100 Tablets (10 x 10 unit dose blister) per carton, Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC: 68084-203-01; Individual Dose NDC: 68084-203-11

Product Quantity:

63,500 tablets

Reason for Recall:

Cross contamination with other products: API contaminated with trace amounts of Acemetacin API.

Recall Number:

D-0536-2026

Code Information:

Lot#: 1027583, Exp 09/30/2027



Product Description:

Primidone Tablets, USP, 50 mg, 100 Tablets (10 x 10 unit dose blister) per carton, Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC: 68084-202-01; Individual Dose NDC: 68084-202-11

Product Quantity:

225,000 tablets

Reason for Recall:

Cross contamination with other products: API contaminated with trace amounts of Acemetacin API.

Recall Number:

D-0537-2026

Code Information:

Lot 1028739, exp 12/31/2027; Lot 1025622, exp 06/30/2027