Enforcement Report - Week of June 17, 2026

Class I Drugs Event

Event ID:
98921

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/12/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/05/2026

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
DOXOrubin Hydrochloride Liposome injection, 50 mg/25 mL (2mg/mL), 25 mL single-dose vials, Sterile, Rx only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol, Gujarat, India, NDC 72603-200-01.

Product Quantity:
675 vials

Reason for Recall:
Presence of Particulate matter: Particulate matter identified as glass.

Recall Number:
D-0580-2026

Code Information:
Lot HAG2581B, expires: 05/31/2027

Class I Drugs Event

Event ID:
99125

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/04/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/17/2026

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Gas-X Extra Strength, SIMETHICONE 125 mg/ANTIGAS, packaged in a) 120 SoftGels (UPC 3 00674 35041 9, b) 72 SoftGels (UPC 3 00439 00572 1), Distributed by: Haleon, Warren, NJ 07059.

Product Quantity:
35,883 boxes/carton

Reason for Recall:
Chemical Contamination: contamination with a diluted propylene glycol-based coolant from a machine leakage during the packaging process.

Recall Number:
D-0595-2026

Code Information:
Lots: a) TL8K, YH9X, YH9Y, Exp. Date. 30Nov2028; b) X78N, Exp. Date 30Nov2028.

Class II Drugs Event

Event ID:
99108

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/04/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/08/2026

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 within the United States

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30mg, 1000 Capsule bottles, Rx only, Manufactured. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Distributed by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-747-10

Product Quantity:
14,729 bottles.

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit

Recall Number:
D-0582-2026

Code Information:
Lot: 241180C, Exp. Date April 2027.

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60mg, packaged in a) 90 Capsules (NDC 51991-748-90); b) 1000 Capsules (51991-748-10), Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.

Product Quantity:
359,676 bottles

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit

Recall Number:
D-0583-2026

Code Information:
Lot: a) 241074C, Exp. Date May 2027; 240317, 240318, 240315C, 240373C, 240370C, 240375C, 240413C, Exp. Date February 2027; 240316,Exp. Date January 2027; 232311, Exp. Date November 2026; b) 240978C, 241052C, Exp. Date April 2027.

Class II Drugs Event

Event ID:
99112

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/22/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zep Inc
350 Joe Frank Harris Pkwy
Emerson, GA 30137
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Zep, Alcohol Sanitizer Spray, Ethanol 70%, Net Contents 55 Gallons 208 Liters, Made in USA, A Zep Inc. Brand, Distributed by: Zap Inc., 350 Joe Frank Harris Parkway, SE, Emerson, GA 30137, NDC 66949-133-85.

Product Quantity:
5 drums

Reason for Recall:
Microbial contamination of sterile products

Recall Number:
D-0586-2026

Code Information:
Batch # E2612116, Exp Date: April 2029.

Class II Drugs Event

Event ID:
99127

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/29/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/11/2026

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz

Camarillo, CA 93012-8601
United States

Distribution Pattern:
Within the U.S Market.

Associated Products

Product Description:
GSMS Incorporated, NIACIN EXTENDED-RELEASE TABLETS, USP, 1,000 MG, 90 tablets, Rx only, Manufactured by Kremers Urban Pharmaceuticals Inc., a subsidiary of Lannett, Inc., Seymour, IN 47274, Packaged by GSMS Incorporated, Camarillo, CA 93012. NDC 51407-268-90.

Product Quantity:
2,961 bottles

Reason for Recall:
Failed Dissolution Specifications: During 12-month long-term stability testing, subject lot was out of specification (low) for stage 3 dissolution at the 24-hour timepoint.

Recall Number:
D-0587-2026

Code Information:
Lots: GS065128, GS065844, GS066695, GS067432, GS067993, expires: 01/31/2027.

Class II Drugs Event

Event ID:
99129

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/01/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/17/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
135 Us Highway 202 206 Ste 15
Bedminster, NJ 07921-2608
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Minocycline Hydrochloride Extended-Release Tablets, USP, 115 mg, 30-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054. NDC: 67877-644-30

Product Quantity:
360 30-count bottles

Reason for Recall:
Failed Dissolution Specifications: An out-of-specification (OOS) result was observed during the 9th month of dissolution test analysis

Recall Number:
D-0597-2026

Code Information:
Lot# 25141635, Exp 4/30/2028

Class III Drugs Event

Event ID:
98997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/14/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/05/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich, IL 60047-8930
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Epinephrine Injection, USP, 1mg/mL, 1 mL single-dose vial, Rx only, Fresenius Kabi, Lake Zurich, IL 60047, NDC 63323-696-02 (vial), NDC 63323-696-25 (carton)

Product Quantity:
898,050 vials

Reason for Recall:
Failed Impurities/Degradations Specifications

Recall Number:
D-0581-2026

Code Information:
Batch # 6133313, 6133314, Exp Date: 06/2026; Batch # 6133315, Exp Date: 07/2026; Batch # 6133682, Exp Date: 09/2026; Batch # 6134812, 6134813, Exp Date: 04/2027.

Class III Drugs Event

Event ID:
99146

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/03/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals, LLC
400 Crossing Blvd Fl 3
Bridgewater, NJ 08807-2863
United States

Distribution Pattern:
Nationwide within the USA.

Associated Products

Product Description:
Primidone Tablets, USP, 50 mg, 100 Tablets per Bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Dosage Unit, Ahmedabad 382213, INDIA. Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC: 53746-544-01

Product Quantity:
27,936 100-count bottles

Reason for Recall:
Cross Contamination with Other Products: due to a potential for cross-contamination with Acemetacin API due to an issue at the API manufacturer.

Recall Number:
D-0585-2026

Code Information:
Lot AM251676, EXP 11/31/2028

Not Yet Classified Drugs Event

Event ID:
99113

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/29/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

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 within the United States

Associated Products

Product Description:
Budesonide Inhalation Suspension, 1mg/2mL, 30 x 2 mL Sterile Single-Dose Ampules (5 Single-Dose Ampules per pouch, 6 pouches per carton, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Baska Ujeti Road, Ujeti Halol-289350, Gujarat, India, NDC 47335-633-49.

Product Quantity:
N/A

Reason for Recall:
Presence of Foreign Substance:This recall has been initiated in response to a product quality complaint reported for black/brown specs and particles within the ampoule solution

Recall Number:
N/A

Code Information:
Lot #: BAG0074A, Exp. Date: 1/31/2027.

Not Yet Classified Drugs Event

Event ID:
99145

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/01/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BEEKEEPER'S NATURALS USA INC.
440 N Barranca Ave # 9223
Covina, CA 91723-1722
United States

Distribution Pattern:
Nationwide within the United States.

Associated Products

Product Description:
BEEKEEPER'S NATURALS Saline Nasal Spray, Sinus Congestion Rinse, Made with Propolis + Xylitol, 1 FL OZ (30 mL) per bottle, Manufactured For: Beekeeper's Naturals USA Inc., Covina, CA 91723

Product Quantity:
1680 units

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
N/A

Code Information:
Lot #: 5950, Exp. Date 02/2028