Enforcement Report - Week of March 26, 2025

Class I Drugs Event

Event ID:
96328

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
One Source Nutrition, Inc,
19863 Interstate 30 S
Benton, AR 72015-6966
United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
Vitality, Fast Acting Male Enhancement Product, Dietary Supplement, a) One Capsule per Packet, b) 6 capsules per bottle, Xtreme Potency.

Product Quantity:
a) 300 individually wrapped capsules b) 20 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Product found to be tainted with undeclared sildenafil and tadalafil.

Recall Number:
D-0281-2025

Code Information:
All lots

Class II Drugs Event

Event ID:
96325

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/27/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amgen, Inc.
1 Amgen Center Dr
Thousand Oaks, CA 91320-1730
United States

Distribution Pattern:
Nationwide in the U.S.A. and Belgium/Luxembourg, Brazil, Chile, Colombia, France/French Guiana, Germany, Ireland, Italy/San Marino, Netherlands, Poland, Spain/Andorra, Sweden, Finland, Switzerland/Liechtenstein, United Kingdom of Great Britain and Northern Ireland, Ireland, Denmark, Canada, Hong Kong, Philippines, Israel, Malaysia, Saudi Arabia, Gibraltar.

Associated Products

Product Description:
Neupogen (filgrastim) For Injection, 300mcg/1 mL, 1 mL Single Dose Vials, Rx Only, For Subcutaneous or Intravenous Use Only, Sterile Solution - No Preservative, Amgen Inc., Thousand Oaks, CA 91320, NDC 55513-530-01 (vial), NDC 55513-530-10 (box).

Product Quantity:
313,620 Vials

Reason for Recall:
Stability data does not support expiry: the products have the potential to be out of specification at the time of expiry of 36-months.

Recall Number:
D-0285-2025

Code Information:
Lot #: 1147300, 1147300A, Exp.: 2/28/2025; 1152064, Exp.:3/31/2025; 1154734, 1156806, Exp.: 8/31/2025; 1159109, Exp.: 10/31/2025; 1163909, Exp.: 2/28/2026; 1164631, Exp.: 5/31/2026; 1171366, 1182097, Exp.:8/31/2026; 1176114, Exp.: 2/28/2027; 1182094, Exp.:7/31/2027.

Product Description:
Neupogen (filgrastim) For Injection, 480 mcg/1.6 mL (300 mcg/1 mL), 1.6 mL single Dose Vial, Rx Only, For Subcutaneous or Intravenous Use Only, Sterile Solution - No Preservative, Amgen Inc. Thousand Oaks, CA 91320, NDC 55513-546-01 (vial), NDC 55513-546-10 (box).

Product Quantity:
258,750 Vials

Reason for Recall:
Stability data does not support expiry: the products have the potential to be out of specification at the time of expiry of 36-months.

Recall Number:
D-0286-2025

Code Information:
Lot 1147308, 1154183, Exp.: 2/28/2025; 1156807, 1160222, Exp.: 6/30/2025; 1160223, 1163912, 1167352, Exp.: 2/28/2026; 1171365, 1175057, 1176250, Exp.: 11/30/2026.

Class II Drugs Event

Event ID:
96369

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/25/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MYLAN PHARMACEUTICALS INC
1311 Pineview Dr
Morgantown, WV 26505-3276
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Prasugrel Tablets, USP, 5 mg, 30-count bottle, Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., NDC 0378-5185-93

Product Quantity:
N/A

Reason for Recall:
Failed Dissolution Specifications - low dissolution results

Recall Number:
D-0280-2025

Code Information:
Lot # 3211073, 3211074, 3211075, Exp 4/30/2026

Class II Drugs Event

Event ID:
96404

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/17/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
MEDLINE INDUSTRIES, LP - Northfield
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Medline Alcohol Prep Pads, 70% Isopropyl Alcohol, 100 Sterile 2-Ply Pads, Single Use Only, Large, www.medline.com, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA, 1-800-MEDLINE, NDC 53329-811-30.

Product Quantity:
6,669,874 pads

Reason for Recall:
Subpotent Drug

Recall Number:
D-0288-2025

Code Information:
SKU: MDS090670, Lot: 61224040057

Product Description:
CURAD Alcohol Prep Pads, Sterile, Medium, 2-Ply, Contents: 5 boxes per Carton, 30 Boxes per Case, Single Use Only, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093, USA, Made in India, www.curad.com, 1-800-633-5463, NDC 53329-827-30.

Product Quantity:
1,639,996 pads

Reason for Recall:
Subpotent Drug

Recall Number:
D-0289-2025

Code Information:
SKU: CUR090737RB, Lot: 61224050002

Class II Drugs Event

Event ID:
96427

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/14/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharma Holding, Inc.
2 Tower Center Blvd Ste 1401
East Brunswick, NJ 08816-1149
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30 mg, 1,000-count bottle, Rx only, Distributed by: Rising Health, LLC, Saddle Brook, NJ 07663, NDC 57237-018-99

Product Quantity:
1223 bottles

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

Recall Number:
D-0277-2025

Code Information:
Lot #: DTB23111A, Exp 8/31/2025

Class II Drugs Event

Event ID:
96428

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc.
1718 Northrock Ct
Rockford, IL 61103-1201
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP, 150 mcg (0.15 mg), Rx Only, 100 Unit Dose Blister Cards of 10 (10 cards of 10 tablets each) per carton, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, Made in India, NDC 51079-445-20.

Product Quantity:
347 Cartons

Reason for Recall:
Super-Potent Drug: Out of specification potency results were obtained.

Recall Number:
D-0290-2025

Code Information:
Lot 3116074, Exp. 09/30/2025

Product Description:
Levothyroxine Sodium Tablets, USP, 125 mcg (0.125 mg), Rx Only, 100 Unit Dose Blister Cards of 10 (10 cards of 10 tablets each) per carton, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, Made in India, NDC 51079-443-20.

Product Quantity:
1,068 cartons

Reason for Recall:
Super-Potent Drug: Out of specification potency results were obtained.

Recall Number:
D-0291-2025

Code Information:
Lot 3115773, Exp. 03/31/2025

Class II Drugs Event

Event ID:
96433

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Slate Run Pharmaceuticals
277 W Nationwide Blvd Ste 260
Columbus, OH 43215-0169
United States

Distribution Pattern:
Product was distributed to 8 distributors who may have further distribute the product nationwide.

Associated Products

Product Description:
Cinacalcet Hydrochloride Tablets 30 mg, 30-count bottle, Rx only, Distr. by: Slate Run Pharma., LLC, Columbus, Ohio 43215, Mfg. by: Piramal Pharma Limited, Madhya Pradesh, India, NDC 70436-007-04

Product Quantity:
56,790 bottles

Reason for Recall:
CGMP deviations: The presence of nitrosamine impurity above the acceptable daily intake limits.

Recall Number:
D-0278-2025

Code Information:
Lot # 07711, Exp 07/2025; 08900, Exp 09/2026; 08899, Exp 09/2026

Product Description:
Cinacalcet Hydrochloride Tablets 60 mg, 30-count bottle, Rx only, Distr. by: Slate Run Pharma., LLC, Columbus, Ohio 43215, Mfg. by: Piramal Pharma Limited, Madhya Pradesh, India, NDC 70436-008-04

Product Quantity:
2,444 bottles

Reason for Recall:
CGMP deviations: The presence of nitrosamine impurity above the acceptable daily intake limits.

Recall Number:
D-0279-2025

Code Information:
Lot # 109797, Exp 11/2026

Class II Drugs Event

Event ID:
96441

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2025

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:
U.S. Nationwide

Associated Products

Product Description:
PRASUGREL TABLETS, 5 mg, 30 tablet bottles, Rx only, packaged by GSMS, Incorporated, Camarillo, CA 93012 NDC 51407-444-30

Product Quantity:
2,601 30-count bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0287-2025

Code Information:
Lot no's: GS059908, GS060228, GS060709, GS061233, GS061704, GS062158, GS062405, Exp.: 04/30/2026

Class II Drugs Event

Event ID:
96465

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/11/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fruit Of The Earth, Inc.
1430 Avenue R
Grand Prairie, TX 75050-1605
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Walgreens Maximum Strength Tinted Acne Treatment Cream 10% Benzoyl Peroxide/Acne Medication, 0.65 oz (18.4g) tube in a carton; Distributed by: Walgreen CO., 200 Wilmot Rd., Deerfield, IL 60015

Product Quantity:
100,970 tubes

Reason for Recall:
Chemical contamination: presence of benzene

Recall Number:
D-0283-2025

Code Information:
Lot #: 4970743B, 4970743C Exp 3/31/2026, 9722793A, Exp 9/30/2026; 8363513A, Exp 12/3/2026; 2822284A, Exp 8/31/2027; 2143554A, Exp 12/31/2027.

Product Description:
CVS Health Concealing Acne Treatment Cream, CVS, 10% benzoyl peroxide, 1 oz (28 g), Distributed by: CVS Pharmacy, Inc

Product Quantity:
112045 tubes

Reason for Recall:
Chemical contamination: presence of benzene

Recall Number:
D-0284-2025

Code Information:
Lot #: 4970743A, Exp 3/31/2026; 9712793A, Exp9/30/2026; 8363513B, Exp 12/31/2026; 1391304A, 5101574A, Exp 5/31/2027; 1292084A, 1292084B, 1292084C, Exp 7/31/2027; 2892384A, Exp 8/31/2027; 6203044A, 6203044B, Exp 10/31/2027; 2153564A, 2153564B, Exp 12/31/2027; 2163564A, Exp 1/31/2028

Class II Drugs Event

Event ID:
96495

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/11/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
Nationwide in the U.S

Associated Products

Product Description:
Ciprofloxacin Ophthalmic Solution USP, 0.3% as base, package in 5 mL bottles, Rx Only, Distributed by: Leading Pharma LLC, Fairfield, NJ. Manufactured by: FDC Limited, Maharashtra, India, NDC 69315-308-05

Product Quantity:
90960 bottles

Reason for Recall:
Defective container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle

Recall Number:
D-0282-2025

Code Information:
Lot: 084A067, Exp 12/31/2025