Enforcement Report - Week of June 18, 2025

Class I Drugs Event

Event ID:
96735

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/14/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/11/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SAINI TRADE INC
1405 N Scottsdale Rd
Tempe, AZ 85288-1714
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Male Ultra, Unleash Your Force, Dietary Supplement,10 capsules per box, Distributed By; Health Fixer, Tempe, AZ 85288, UPC B0CMQ4FTHG.

Product Quantity:
3000 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA: Laboratory analysis found the product to be tainted with undeclared propoxyphenylsildenafil and sildenafil.

Recall Number:
D-0463-2025

Code Information:
All Lots Lot #: KT-1ST-43-01-10-2025, Exp. 01/10/2027

Product Description:
MALEXTRA, Recharge with Extra, Dietary Supplement, 10 capsules per box, Distributed by: Health Fixer, Tempe, AZ 85288, UPC B0CWKZ6ZP3.

Product Quantity:
500 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA: Laboratory analysis found the product to be tainted with undeclared propoxyphenylsildenafil and sildenafil.

Recall Number:
D-0464-2025

Code Information:
All lots Lot #: KT-1ST-43-01-04/2026, Exp. 04/25/2026

Product Description:
ELECTRO BUZZ, Dietary Supplement, 10 capsules per box, Distributed By: Health Fixer, Tempe, AZ 85288, UPC B0DK68LF6J.

Product Quantity:
300 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA: Laboratory analysis found the product to be tainted with undeclared chloropretadalafil,

propoxyphenylsildenafil, and sildenafil.

Recall Number:
D-0465-2025

Code Information:
All lots Lot #: KT-1ST-43-01-07/2024, Exp. 10/15/2026

Product Description:
ULTRA ARMOR, My Armor My Power, Dietary Supplement, 10 capsules per box, Distributed by Health Fixer, Tempe, AZ 85288, UPC B0CYJ7Y5H9.

Product Quantity:
500 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA: Laboratory analysis found the product to be tainted with undeclared propoxyphenylsildenafil and sildenafil.

Recall Number:
D-0466-2025

Code Information:
All lots Lot #: KT-1ST-43-01-10/2025, Exp. 01/10/2027

Product Description:
Male Ultra Pro, Unleash Your Force 2, 10 capsules per box, Distributed by: Health Fixer Tempe AZ 85288, UPC B0CZN7C6YH.

Product Quantity:
300 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA: Laboratory analysis found the product to be tainted with undeclared propoxyphenylsildenafil and sildenafil.

Recall Number:
D-0467-2025

Code Information:
All lots Lot #: KT-1ST-43-0110/2025, Exp. 03/15/2026

Class II Drugs Event

Event ID:
96840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/06/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alembic Pharmaceuticals Limited
Formulation Division, Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol
Panchmahal
India

Distribution Pattern:
Distributed Nationwide and in PR

Associated Products

Product Description:
Celecoxib Capsules, 200 mg, 500-count bottle, Rx only, Manufactured by: Alembic Pharmaceuticals Limited (Formulation Division), Panelav 389350, Gujarat, India, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, NDC 62332-142-71

Product Quantity:
2,946 500-count bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules; customer complaint found one Tadalafil 5mg tablet inside a sealed 500-count bottle of Celecoxib 200mg capsule

Recall Number:
D-0459-2025

Code Information:
Batch 2405014780, Exp. Date: Sep. 30, 2027

Class II Drugs Event

Event ID:
96866

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/09/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski, TN 38478-2403
United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Chlorthalidone Tablets, USP, 25 mg, 50 Tablets (5x10) Unit Dose cards per carton, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 50268-167-15

Product Quantity:
962 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0461-2025

Code Information:
Lot # 47947, Exp 05/31/2026

Class II Drugs Event

Event ID:
96888

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/09/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski, TN 38478-2403
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Celecoxib Capsules, 200 mg, 50 Capsules (5x10) Unit Dose per carton, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 50268-169-15

Product Quantity:
3,817 50-count cartons

Reason for Recall:
Presence of Foreign Tablets/Capsules: manufacturer recalled because one tadalafil 5mg tablet was found in 500 count bottle of Celecoxib 200 mg capsules

Recall Number:
D-0460-2025

Code Information:
Lot #47881, Exp 05/31/2026

Class II Drugs Event

Event ID:
96912

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/23/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany, NJ 07054-3707
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Cephalexin for Oral Suspension, USP, 125 mg per 5 mL, 100 mL (when mixed), Rx Only, Manufactured by: Alkem Laboratories Ltd., India, Distributed by: Ascent Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-544-88

Product Quantity:
48,936 - 100 mL bottles

Reason for Recall:
Failed Impurities/Degradation Specifications An out-of-specification result was observed in the related substance test at the sixth month of stability analysis. The individual impurity was identified to be Cephalexin Glucose Adduct.

Recall Number:
D-0468-2025

Code Information:
Lot #: 23141828, 23141829, Exp Date: 5/31/2025; 23142342, Exp Date: 6/30/2025; 23142708, Exp Date: 7/31/2025; 23144035, Exp Date:

10/31/2025; 23144270, Exp Date: 11/302025; 24140026, Exp Date: 12/31/2025

Product Description:
Cephalexin for Oral Suspension, USP, 125 mg per 5 mL, 200 mL (when mixed), Rx Only, Manufactured by: Alkem Laboratories Ltd., India, Distributed by: Ascent Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-544-68

Product Quantity:
10,620 - 200 mL bottles

Reason for Recall:
Failed Impurities/Degradation Specifications An out-of-specification result was observed in the related substance test at the sixth month of stability analysis. The individual impurity was identified to be Cephalexin Glucose Adduct.

Recall Number:
D-0469-2025

Code Information:
Lot #: 23142343, Exp Date: 6/30/2025; 23143526, Exp Date: 9/30/2025; 23144036, Exp Date: 10/31/2025; 23144269, Exp Date: 11/30/2025; Lot 24140027, Exp Date: 12/31/2025; 24144282, Exp Date: 10/31/2026

Class III Drugs Event

Event ID:
96884

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/19/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide USA and PR

Associated Products

Product Description:
Ezetimibe and Simvastatin Tablets, 10mg/40mg, 90-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Madya Pradesh, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-323-90

Product Quantity:
6,759 Con - 90 bottle pack

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification (OOS) for related substances test for Anhydro Simvastatin at the 06-month time point during long-term stability study.

Recall Number:
D-0462-2025

Code Information:
Lot #: 17240195, Exp 01/31/2026.

Class III Drugs Event

Event ID:
96979

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Church Road
Mumbai
India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Levothyroxine Sodium Tablets, USP 112 mcg (0.112mg), 1000 tablets, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540. Manufactured by: Macleods Pharmaceuticals Ltd. Sarigam, Valsad, Gujarat, India, NDC 33342-398-44.

Product Quantity:
1,344- 1000 count bottles

Reason for Recall:
Presence of a foreign substance: black hair found embedded in tablet.

Recall Number:
D-0470-2025

Code Information:
Lot #: MLF2401A, Exp 01/31/2026

Not Yet Classified Drugs Event

Event ID:
96964

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/30/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

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:
IL, PA, & MS

Associated Products

Product Description:
Icosapent Ethyl Capsules 1 gram, 120 Capsules per Bottle, Rx Only, Manufactured by Doppel Farmaceutici s.r.l., Piacenza, Italy, Distributed by Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1592-7.

Product Quantity:
11,616 bottles

Reason for Recall:
Failed Tablet/Capsule specifications; a product complaint was reported for burnt or melted capsules. This was determined to be a result of oxidation by leakage of capsule contents.

Recall Number:
N/A

Code Information:
Lot #s: B237040, B237041, Exp 10/31/2025

Not Yet Classified Drugs Event

Event ID:
96985

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/02/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
N/A

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Tablets, USP, 400 mg/80 mg, Rx Only, a) 100 Tablets per Bottle, NDC: 65162-271-10, b) 500 Tablets per Bottle, NDC: 65162-271-50, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Oral Solid Dosage Unit, Ahmedabad, 382213, INDIA, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807.

Product Quantity:
6396 bottles

Reason for Recall:
Microbial contamination of non-sterile products: tablets may exhibit black spots due to microbial contamination.

Recall Number:
N/A

Code Information:
Lot #s: a) AM241019, AM241020, Exp. 06/30/2027 b) AM241019A, Exp 06/30/2027