Enforcement Report - Week of February 11, 2026

Class I Drugs Event

Event ID:
97526

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/10/2026

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Green Lumber Holdings, LLC
2855 E Coast Hwy Ste 228
Corona Del Mar, CA 92625-2200
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Green Lumber Natural Fuel For Men capsule, packaged in 2, 4, 10, and 30-count blister packs. GreenLumber.com, 2618 San Miguel Drive, Suite #296, Newport Beach, CA 92660

Product Quantity:
N/A

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found this product to contain tadalafil

Recall Number:
D-0304-2026

Code Information:
LOT308EXP03/28

Class I Drugs Event

Event ID:
98165

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/22/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/12/2026

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
HANDELNINE GLOBAL LLC
South Plainfield 4300 S Clinton Ave
South Plainfield, NJ 07080-1219
United States

Distribution Pattern:
Product was distributed to one customer in NY.

Associated Products

Product Description:
Rheumacare capsules, 30 count bottle, Mfg in India by: Virgo UAP Pharma Pvt. Ltd., Ahmedabad, India UPC 8 904218 700313

Product Quantity:
4 bottles /30 capsules each

Reason for Recall:
CGMP Deviations: product found to contain lead.

Recall Number:
D-0332-2026

Code Information:
Lot: CAM040, Exp. 06/30/2029 Lot: CAL079-N, Exp. 09/30/2028

Class II Drugs Event

Event ID:
98323

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/21/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/30/2026

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:
US Nationwide and PR.

Associated Products

Product Description:
Bisoprolol Fumarate and Hydrochlorothiazide tablets, USP, 2.5 mg/6.25 mg, 100-count bottle, Rx Only, Manufactured by: UNICHEM LABORATORIS LTD., Pilerne Ind. Estate, Pilerne, Bardez, Goa 403 511, India, Manufactured for: UNICHEM PHARMACEUTICALS (USA), INC., East Brunswick, NJ 08816, NDC 29300-187-01

Product Quantity:
N/A

Reason for Recall:
cGMP Deviations: recall due to not meeting the N-Nitroso Bisoprolol impurity specification limits.

Recall Number:
D-0301-2026

Code Information:
Lot # GBHL24005A, Exp Date: 09/2026

Class II Drugs Event

Event ID:
98345

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/26/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/11/2026

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Granules Pharmaceuticals Inc.
3701 Concorde Pkwy
Chantilly, VA 20151-1126
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Trazodone Hydrochloride, USP, 50 mg, 100-Count Bottle, Rx only, Manufactured by: Granules India Limited, Hyderabad, 500 081, India, Manufactured for: Granules Pharmaceuticals Inc., Chantilly, VA 20151, NDC 70010-231-01.

Product Quantity:
71424 bottles.

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0305-2026

Code Information:
Batch # 6160008A, Exp Date: 12/31/2026

Class II Drugs Event

Event ID:
98351

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/27/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2026

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:
US Nationwide.

Associated Products

Product Description:
Diclofenac Sodium, Topical Gel, 3%, 100 g tube, Rx only, Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1, Dist. by Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1363-7

Product Quantity:
N/A

Reason for Recall:
Failed Viscosity Specifications: Out of Specification (OOS) [slightly lower than the limit] result in viscosity for Diclofenac Sodium Gel, 3%.

Recall Number:
D-0342-2026

Code Information:
Lot # AD92721, Exp Date: 3/31/2027.