Enforcement Report - Week of February 26, 2025

Class I Drugs Event

Event ID:
96121

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/20/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Provepharm Inc.
100 Springhouse Dr Ste 105
Collegeville, PA 19426-4709
United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Phenylephrine HCl Injection, USP 100 mg/10 mL (10 mg/mL) vials, Rx only, Pharmacy Bulk Package (supplied as a single unit), Dist. by: Provepharm, Inc., Collegeville, PA 19426

Product Quantity:
24640 vials

Reason for Recall:
Presence of Particulate Matter.

Recall Number:
D-0230-2025

Code Information:
Lot# 24020027, Exp Date: 12/31/2025

Class I Drugs Event

Event ID:
96222

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/20/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alvogen, Inc
44 Whippany Rd Ste 300
Morristown, NJ 07960-4558
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Fentanyl Transdermal System CII, 25mcg/h, packaged in a pouch, further packaged in 5-count carton, Rx only, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058, Manufactured by: Kindeva Drug Delivery L/P, Northridge, CA 91324, NDC 47781-424-47.

Product Quantity:
112,128 cartons (5 pouches/carton)

Reason for Recall:
Defective delivery system - patches could be multi-stacked, adhered one on top of the other, in a single product pouch.

Recall Number:
D-0245-2025

Code Information:
Lot #: 108319, Exp: 04/30/2027

Class II Drugs Event

Event ID:
96151

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/19/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne, TN 37086-3606
United States

Distribution Pattern:
Nationwide U.S. and Puerto rico

Associated Products

Product Description:
Lorazepam Tablets, USP, 0.5mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-904 Leading Pharma, LLC., Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6007-61

Product Quantity:
82,281 cartons

Reason for Recall:
Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during routine stability testing for Assay and Impurities.

Recall Number:
D-0226-2025

Code Information:
Lot #s: N01424, N01425, Exp 03/31/2025; N01659, N01660, Exp 08/31/2025; N01668, 09/2025; N01679, N01704, N01745, Exp 10/31/2025; N01856, Exp 02/28/2026; N01973, Exp 05/31/2026; N02079, Exp 08/31/2026.

Product Description:
Lorazepam Tablets, USP, 1mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-905 Leading Pharma, LLC., Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6008-61.

Product Quantity:

94,349 cartons

Reason for Recall:
Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during routine stability testing for Assay and Impurities.

Recall Number:
D-0227-2025

Code Information:
Lot #s: N01419, N01420, N01421, Exp 03/31/2025; N01663, Exp 06/30/2025; N01664, Exp 08/31/2025; N01673, Exp 09/30/2025; N01688, Exp 08/31/2025; N01747, N01748, N01749, Exp 11/30/2025; N01792, Exp 12/31/2025; N01857, Exp 02/28/2026; N01974, Exp 05/31/2026; N02081, Exp 08/31/2026.

Product Description:
Lorazepam Tablets, USP, 2mg, Unit Dose, 100 tablets per carton (10 x 10 blister packs), Rx only, The drug product contained in this package is from NDC # 69315-906 Leading Pharma, LLC., Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 26268 USA, NDC: 0904-6009-61.

Product Quantity:
27,525 cartons

Reason for Recall:
Failed impurities/degradation specifications and Sub-potent Drug: Out-of-specification results were obtained during routine stability testing for Assay and Impurities.

Recall Number:
D-0228-2025

Code Information:
Lot #s: N01422, N01423, Exp 03/31/2025; N01661, N01662, Exp 09/30/2025; N01746, N01750, Exp 10/31/2025; N01876, N01877, Exp 03/31/2026; N01899, N01900, N01975, Exp 04/30/2026.

Class II Drugs Event

Event ID:
96194

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/20/2025

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 within the U.S

Associated Products

Product Description:
Atomoxetine Capsules, USP, 10 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-265-30.

Product Quantity:
70,032 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:

D-0231-2025

Code Information:
Lot Numbers: 19232368, Exp:5/2025; 19235088, Exp.: 11/2025; 19241447, Exp.: 3/2026; 19243146, Exp.: 7/2026.

Product Description:
Atomoxetine Capsules, USP, 18 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-266-30.

Product Quantity:
56,208 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0232-2025

Code Information:
Lot Numbers: 19233756, Exp.: 8/2025; 19235111, Exp.: 11/2025; 19242167, Exp.: 5/2026; 19242180, Exp.: 5/2026.

Product Description:
Atomoxetine Capsules, USP, 25 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-267-30.

Product Quantity:
175,920 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0233-2025

Code Information:
Lot Numbers: 19233792, Exp.: 8/2025; 19233795, Exp.: 8/2025; 19234258, Exp.: 9/2025; 19240912, Exp.: 2/2026; 19241476, 19241477, Exp.: 3/2026; 19242599, Exp.: 6/2026; 19243163, 19243162, Exp.:7/2026;19243884, 19243887, Exp.:9/2026.

Product Description:
Atomoxetine Capsules, USP, 40 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-268-30.

Product Quantity:
190,320 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0234-2025

Code Information:
Lot Numbers: 19234109, Exp.: 9/2025; 19234897, Exp.: 11/2025; 19240501, Exp.: 1/2026; 19241489, Exp.: 3/2026; 19241806, Exp.: 4/2026.

Product Description:
Atomoxetine Capsules, USP, 60 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-269-30.

Product Quantity:
80,160 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0235-2025

Code Information:
Lot Numbers: 19234630, Exp.: 10/2025; 19240528, 19240529, Exp.: 1/2026.

Product Description:
Atomoxetine Capsules, USP, 80 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India,

NDC 68462-270-30.

Product Quantity:
87,600 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0236-2025

Code Information:
Lot Numbers: 19234153, Exp.: 9/2025; 19234900, 19234929, Exp.: 11/2025; 19240936, 19240942, Exp.: 2/2026; 19243199, 19243190, Exp.:7/2026; 19244013, 19244014, Exp.: 9/2026.

Product Description:
Atomoxetine Capsules, USP, 100 mg, 30 capsule bottles, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., NJ, USA, Product of India, NDC 68462-271-30.

Product Quantity:
39,168 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0237-2025

Code Information:
Lot Numbers: 19234955, 19234956, Exp.: 11/2025; 19240971, Exp.: 2/2026; 19241864, Exp.: 4/2026.

Product Description:
Atomoxetine Capsules, USP, 10 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-755-01.

Product Quantity:
120,000 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0238-2025

Code Information:
Lot Numbers: 19232356, Exp.: 5/2025; 19233198, Exp.: 7/2025; 19234213, 19234232, Exp.: 9/2025; 19241445, Exp.: 3/2026; 19243033, 19243121, Exp.: 7/2026.

Product Description:
Atomoxetine Capsules, USP, 18 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-756-01.

Product Quantity:
119,040 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0239-2025

Code Information:
Lot Numbers: 19233228, 19233227, Exp.: 7/2025; 19233757, Exp.: 8/2025; 19234229, Exp.: 9/2025; 19235090, Exp.: 11/2025; 19241471, Exp.:3/2026; 19242180, Exp.: 5/2026.

Product Description:
Atomoxetine Capsules, USP, 25 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-757-01.

Product Quantity:
133,824 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0240-2025

Code Information:
Lot Numbers: 19232506, 19232397, 19232415, Exp.: 5/2025; 19233791, Exp.: 8/2025; 19234248, Exp.: 9/2025; 19240909, Exp.: 2/2026; 19242598, Exp.:6/2026; 19243163, 19243122, Exp.: 7/2026; 19243884, Exp.: 9/2026.

Product Description:
Atomoxetine Capsules, USP, 40 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-758-01.

Product Quantity:
233,040 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0241-2025

Code Information:
Lot Numbers: 19232540, 19232524, 19232553, Exp.: 5/2025; 19240510, Exp.: 1/2026; 19241489, Exp.: 3/2026; 19243905, 19243935, Exp.: 9/2026.

Product Description:
Atomoxetine Capsules, USP, 60 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-759-01.

Product Quantity:
53,952 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0242-2025

Code Information:
Lot Numbers: 19234630, Exp.: 10/2025; 19240529, Exp.: 1/2026.

Product Description:
Atomoxetine Capsules, USP, 80 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-760-01.

Product Quantity:
58,416 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0243-2025

Code Information:
Lot Numbers: 19233234, 19233253, Exp.: 7/2025; 19234154, Exp.: 9/2025; 19243185, Exp.: 7/2026; 19243951, 19243974, Exp.: 9/2026.

Product Description:
Atomoxetine Capsules, USP, 100 mg, 30 capsule bottles, Rx Only, Manufactured for: Northstar Rx LLC., Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Goa, India, NDC 16714-761-01.

Product Quantity:
58,368 bottles

Reason for Recall:
CGMP Deviations: presence of N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

Recall Number:
D-0244-2025

Code Information:
Lot Numbers: 19233270, 19233278, 19233285, Exp.: 7/2025; 19233806, Exp.: 8/2025; 19240954, Exp.: 2/2026; 19241854, Exp.: 4/2026.

Class II Drugs Event

Event ID:
96232

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/19/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron Compounding Services
8710 E 34th St N
Wichita, KS 67226-2636
United States

Distribution Pattern:
Distributed in PA

Associated Products

Product Description:
fentaNYL Citrate In Sodium Chloride 1600mcg/100mL (16 mcg per mL) CII, Single use 100mL IV Bag, Fagron Sterile Services, 8710 E 34th St N, Wichita, KS 67726 Bar Code 71266-5060-01

Product Quantity:
1330 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0225-2025

Code Information:
Lot # C274-000040409, Exp 03/22/2025

Class II Drugs Event

Event ID:
96247

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/20/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Silodosin Capsules, 8mg, 90-count bottle, Rx only, Manufactured for: AvKare, Pulaski, TN 38478, Manufactured by: Amneal Pharmaceuticals of NY, LLC, NY 11719, NDC 42291-778-90

Product Quantity:
1266 bottles

Reason for Recall:
Subpotent Drug: Out of Specification (OOS) result for De hydro Impurity (0.654%) for 18 M Stability sample and low assay 94.9% (specification of NLT 95.0% NMT 105%)

Recall Number:
D-0229-2025

Code Information:
Lot#: BC20223A, Exp. March 31, 2025.