Enforcement Report - Week of October 29, 2025

Class II Drugs Event

Event ID:
97629

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Graviti Pharmaceuticals Private Limited
E & 621 Patancheru Mandal Isnapur Village Rd; Survey No 621
Hyderabad
India

Distribution Pattern:
Product was distributed to 1 distributor and 16 wholesalers/pharmacy retailers nationwide.

Associated Products

Product Description:
Bupropion Hydrochloride Extended-Release Tablets USP (XL), 300 mg, 30-count bottles, Rx Only, Mfd. by: Graviti Pharmaceuticals Private Limited, Sangareddy, Telangana, India, Dist. by: Rising Phar, NDC 16571-863-03.

Product Quantity:
46,512/30 count bottles

Reason for Recall:
Failed Tablet/Capsule Specifications

Recall Number:
D-0037-2026

Code Information:
Batch # BPB124341A, Exp date: 10/2026

Class II Drugs Event

Event ID:
97711

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/01/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aspiro Pharma Limited
Survey No. 321, Biotech Park, Phase Iii Karkapatla Village, Markook (Mandal)
Siddipet (District)
India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ketorolac Tromethamine Injection, USP, 60 mg/2 mL (30 mg/mL), 2 mL Single-Dose Vial, For Intramuscular Use Only, Rx only, Mfd. for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Mfd. by: ASPIRO PHARMA LIMITED, Telangana - 502281, INDIA., U.S. Contact Number: 1-866-495-1995, NDC 31722-307-25 (Carton), 31722-307-02 (Vial label).

Product Quantity:
N/A

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

Recall Number:
D-0036-2026

Code Information:
Lot #: AS1240347A, Exp Date 09/2026; AS1240144A, Exp Date 05/2026; AS1240145A, AS1240146A, Exp Date 06/2026; AS1250295A, Exp Date 05/2027.

Class II Drugs Event

Event ID:
97729

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/01/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Church & Dwight Co., Inc.
500 Charles Ewing Blvd
Ewing, NJ 08628-3448
United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
ZICAM" MEDICATED FRUIT DROPS ELDERBERRY FLAVOR, 25-drops per bottle, Distributed by: Church & Dwight Co., Inc. Ewing, NJ 08628, NDC 10237-469-25

Product Quantity:
21,912 bottles

Reason for Recall:
Labeling: Label Mix-up: The product in the bottle contains elderberry and the label failed to indicate the inclusion of elderberry as an ingredient.

Recall Number:
D-0095-2026

Code Information:
Lot#: BE51396303, Exp. Date 2027/05

Class II Drugs Event

Event ID:
97766

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/20/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
USV Private Limited
H-13, 16, 16a, 17, 18, 19, 20, 21 & E-22, Oidc, Mahatma Gandhi Udyog Nagar
Dabhel, Daman
India

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Olopatadine Hydrochloride Ophthalmic Solution USP 0.1 %, 5 mL (0.17 FL OZ) bottles, Manufactured for: SOLA PHARMACEUTICALS LLC, Baton Rouge, LA 70810, NDC 70512-0520-05

Product Quantity:
8,952 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: The result for 'Any individual unspecified impurity' exceeds the specification limit.

Recall Number:
D-0034-2026

Code Information:
Lot #: 35000409, Exp. Date 01/2026

Class II Drugs Event

Event ID:
97777

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
The Harvard Drug Group LLC
7000 Cardinal Pl
Dublin, OH 43017-1091
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Gabapentin Capsules, USP, 100 mg, 100 Capsules (10 x 10 blister packs), Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268, USA, NDC 0904-6665-61

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications: an out of specification result obtained during routine stability testing for Highest Unknown Impurity .

Recall Number:
D-0030-2026

Code Information:
Lot # M04950, Exp Date: 01/2026; Lot # M04989, M04990, Exp Date: 02/2026; Lot # M05056, Exp Date: 04/2026; Lot # M05150, Exp Date: 07/2026; Lot # M05290, Exp Date: 11/2026; Lot # M05312, M05342, Exp Date: 01/2027; Lot # M05369, M05386, Exp Date: 02/2027.

Product Description:
Gabapentin Capsules, USP, 100 mg, 10 Capsules (10 x 1 blister pack), Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268, USA, NDC 0904-6665-61 (Blister pack), NDC 55154-3363-0 (Outer Bag).

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications: an out of specification result obtained during routine stability testing for Highest Unknown Impurity .

Recall Number:
D-0031-2026

Code Information:
Lot # M04989A [Bag], M04989 [Blister Pack], Exp Date: 02/2026; Lot # M05056A [Bag], M05056 [Blister Pack], Exp Date: 04/2026; Lot # M05150A [Bag], M05150 [Blister Pack], Exp Date: 07/2026; Lot # M05312A [Bag], M05312 [Blister Pack], and M05342A [Bag], M05342 [Blister Pack], Exp Date: 01/2027.

Class II Drugs Event

Event ID:
97778

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/22/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company Inc.
1101 C Ave W
Seymour, IN 47274-3342
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Niacin Extended-release Tablets, USP, 1,000 mg, Rx Only, 90 Tablets per bottle, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC: 62175-322-46

Product Quantity:
46,848 90-count bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0096-2026

Code Information:
Lot, expiry: 21264027A, Exp 10/30/2025; 22266446A, Exp 12/31/2025; 22266901A, Exp 02/28/2026; 22267553A, 22267554A, Exp 03/31/2026; 22267555A, Exp 02/28/2026; 22267992A, Exp 04/30/2026; 22267993A, 22267994A, Exp 05/31/2026

Class II Drugs Event

Event ID:
97811

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/29/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093-2753
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Medline, Alcohol Prep Pads (2-Ply Pad, 70% Isopropyl Alcohol), 100 eaches per box, 10 boxes per case (1,000 eaches per case), Single Use Only, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL, 60093 USA, NDC 55329-811-30.

Product Quantity:
222,800 eaches

Reason for Recall:
Subpotent Drug

Recall Number:
D-0035-2026

Code Information:
Lot #: 61224040057

Class II Drugs Event

Event ID:
97831

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/09/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/23/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
ibspot
1414 Willow Ave
Elkins Park, PA 19027-3147
United States

Distribution Pattern:
WY and VA

Associated Products

Product Description:
Taoscare Motion Sickness Patches 36-count box, Henan Xinyongtal Medical Technology., Ltd., Address: he nan sheng zhou kou shi huai yang xian

gong ye yuan qu, X003SR097N

Product Quantity:
3 boxes

Reason for Recall:
Marketed Without an Approved NDA/ANDA

Recall Number:
D-0098-2026

Code Information:
none

Class II Drugs Event

Event ID:
97839

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/23/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bristol-Myers Squibb Company
1 Squibb Dr
New Brunswick, NJ 08901-1588
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Opdualag (nivolumab and relatlimab-rmbw) injection, 240 mg and 80 mg/20 mL (12mg and 4mg/mL),Single Dose Vial, RX Only, Bristol-Myers Squibb Company, Princeton, NJ 08543, NDC 0003-7125-11

Product Quantity:
12,778 total vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0097-2026

Code Information:
Lot: 033A23B, Expiry: 4/30/2026

Class III Drugs Event

Event ID:
97573

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/12/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
JB Chemicals and Pharmaceuticals Ltd
Neelam Centre A Wing A B Wing 4th Floor; Hind Cycle Road
Mumbai
India

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Cetirizine Hydrochloride Tablets USP 10 mg, 100 Tablets bottles, Manufactured by: Unique Pharmaceuticals Labs, (A Div. of J.B. Chemicals & Pharmaceuticals, Ltd.), Mumbai 400 030, India. Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816, NDC 16571-402-10.

Product Quantity:
9936 bottles

Reason for Recall:
Tablet/Capsules Imprinted with Wrong ID

Recall Number:
D-0032-2026

Code Information:
Lot # PY925014A; Exp. 1/31/2028

Product Description:
Cetirizine Hydrochloride Tablets USP 10 mg, 500 Tablets bottles, Manufactured by: Unique Pharmaceuticals Labs, (A Div. of J.B. Chemicals & Pharmaceuticals, Ltd.), Mumbai 400 030, India. Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816, NDC 16571-402-50

Product Quantity:
13,440 bottles

Reason for Recall:
Tablet/Capsules Imprinted with Wrong ID

Recall Number:
D-0033-2026

Code Information:
Lot # PY925014, PY925013, Exp. 1/31/2028