# Enforcement Report - Week of September 17, 2025

## Class II Drugs Event

**Event ID:**
97345

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/27/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/10/2025

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Atlantic Management Resources Ltd.
39 Harvey Ln
Westborough, MA 01581-3013
United States

**Distribution Pattern:**
Product was distributed via the internet.

### Associated Products

**Product Description:**
Neuroquell & Neuroquell Plus, .22 fl. Oz (6.6mL),Mfg. For/Dist. By Claire Ellen Products, P.O. Box 901 Westboro, MA 01581 USA, NDC 66233712-01

**Product Quantity:**
72 containers

**Reason for Recall:**
cGMP violations

**Recall Number:**
D-0629-2025

**Code Information:**
Lot # B-02 Batch #: 1087920520 Product # R937 BBE#31-05-21( May 31, 2021) Batch # 1087920920 Product # R937 BBE# 31-05-21 (May 31, 2021)

## Class II Drugs Event

**Event ID:**
97348

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
07/30/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/05/2025

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

**Recalling Firm:**
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir, NC 28645-3618
United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
4.2% Sodium Bicarbonate Injection, USP, 5 mEq/10 mL (0.5 mEq/mL), For Intravenous Use Only, 10 mL Single Dose Vial, Rx Only, Manufactured and Distributed by: Exela Pharma Sciences, LLC, Lenoir, NC 28645 USA, NDC 51754-5012-1 (vial); 51754-5012-4 (carton)

**Product Quantity:**
N/A

**Reason for Recall:**
Failed Impurities/Degradation Specifications: out of specification results for arsenic in the impurities tested.

**Recall Number:**
D-0620-2025

**Code Information:**
Lot # 10004077, Exp. 02/28/2026

## Class II Drugs Event

**Event ID:**
97405

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
02/13/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/08/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
World Perfumes Inc.
2360 Nw 150th St
Opa Locka, FL 33054-2706
United States

**Distribution Pattern:**
FL

## Associated Products

**Product Description:**
Iodo Blanco Iodides, First Aid Antiseptic, Mercury Free, Iodine 2%, First Aid Antiseptic, Contains 1 fl. oz (30 ml) per bottle, Distributed by: Essential Products, www.essentialproductsusa.com, NDC: 70242-109-01

**Product Quantity:**
3,900 bottles

**Reason for Recall:**
Defective Container: broken or leaking bottles.

**Recall Number:**
D-0622-2025

**Code Information:**
Lot 230619, Exp 06/30/2026

## Class II Drugs Event

**Event ID:**
97425

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/08/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/08/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Breckenridge Pharmaceutical, Inc.
200 Connell Dr Ste 4200
Berkeley Heights, NJ 07922-2805
United States

**Distribution Pattern:**
AZ, IN, NJ

## Associated Products

**Product Description:**
Duloxetine Delayed-Release Capsules, USP, 30 mg, 1,000 Capsules per bottle, Rx Only, Manufactured by: Towa Pharmaceutical Europe, S.L., Martorelles, (Barcelona), Spain. Manufactured for: Quallent Pharmaceuticals Health LLC, Grand Cayman, Cayman Islands. NDC: 82009-030-10

**Product Quantity:**
3,591 bottles

**Reason for Recall:**
CGMP deviations: N-nitroso-duloxetine impurity above the proposed interim limit.

**Recall Number:**
D-0621-2025

**Code Information:**
Lot 240927C, Exp 04/30/2027

## Class II Drugs Event

**Event ID:**
97431

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/13/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/10/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Sandoz Inc
100 College Rd W
Princeton, NJ 08540-6604
United States

**Distribution Pattern:**
Product was distributed to one consignee in CA.

## Associated Products

**Product Description:**
Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension Rx Only, For Use in Ears Only, Manufactured By: Novartis Manufacturing NV, Belgium, Distributed by: Sandoz, Inc., Princeton, NJ, NDC# 0781-6186-67, Carton NDC# 0781-6186-67

**Product Quantity:**
1,680 bottles

**Reason for Recall:**
Temperature Abuse

**Recall Number:**
D-0626-2025

**Code Information:**
Lot # VNF35A, Exp.08/31/2026

## Class II Drugs Event

**Event ID:**
97461

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/19/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/11/2025

**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:**
OH

## Associated Products

**Product Description:**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, 10mg, 100 Tablets per bottle, Rx only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136, NDC 0527-0762-37.

**Product Quantity:**
4,848 bottles

**Reason for Recall:**
Presence of Foreign Tablet/Capsule: Two (2) bottles labeled as Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, 10mg, 100ct, contained one (1) tablet of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, 5 mg.

**Recall Number:**
D-0642-2025

**Code Information:**
Lot#: 25283185A. Expiry: 02/28/2027

## Class II Drugs Event

**Event ID:**
97498

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/22/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/11/2025

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
GRACE & FIRE PTY LTD

19 Dover Street
Cremorne
Australia

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Ultra Violette, Velvet Screen SPF 50, Blurring Mineral Skinscreen, Zinc Oxide 22.75%, a) 15 mL, 0.5 fl. oz. per tube, NDC 84803-106-01, UPC 9355909006068, b) 50 mL, 1.7 fl. oz. per tube, NDC 84803-106-02, UPC 9355909005924, Distributed by: Grace & Fire USA Inc., 251 Little Falls Drive, New Castle Wilmington, Delaware 19808.

**Product Quantity:**
49,275 tubes

**Reason for Recall:**
Subpotent/Super-potent Product: Testing of the SPF 50 sunscreen revealed inconsistency in SPF results ranging from SPF 4, 10, 21, 26, 33, 60, 61, and 64.

**Recall Number:**
D-0640-2025

**Code Information:**
Lot #s: a) 15 mL tubes: A2455, exp 12/31/2026; b) 50 mL tubes: A2453A, A2453B, exp 11/30/2026; A2454A, exp 12/31/2026; A2550, exp 02/28/2027

**Product Description:**
Ultra Violette Mini SPF Mates kit includes: Velvet Screen SPF 50 Blurring Mineral SkinScreen, Zinc Oxide 22.75%, 15 mL, 0.5 fl. oz. per tube, Supreme Sunscreen SPF 50, 15 mL 0.5 fl. oz. per tube, Distributed by: Grace & Fire USA Inc., 251 Little Falls Drive, New Castle Wilmington, Delaware 19808, NDC 84803-110-01 (15 mL Velvet Screen), UPC 9355909005757.

**Product Quantity:**
44,497 tubes

**Reason for Recall:**
Subpotent/Super-potent Product: Testing of the SPF 50 sunscreen revealed inconsistency in SPF results ranging from SPF 4, 10, 21, 26, 33, 60, 61, and 64.

**Recall Number:**
D-0641-2025

**Code Information:**
Lot #s: A2453, exp 11/30/2026; A2454, exp 12/31/2026

## Class II Drugs Event

**Event ID:**
97510

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/27/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/08/2025

**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:**
MS, OH, LA, and Puerto Rico

## Associated Products

**Product Description:**
Succinylcholine Chloride Injection, USP 200 mg/10 mL (20 mg/mL), Rx only, 10 mL Multiple-dose Vial, Sterile, Manufactured by Zydus Lifesciences Ltd, Vadodara, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1377-1 (vial), NDC 70710-1377-2 (carton).

**Product Quantity:**
270,125 Vials

**Reason for Recall:**
Failed Impurities/Degradation Specifications: Out-of-Specification test results obtained for any individual unknown degradation impurity.

**Recall Number:**
D-0623-2025

**Code Information:**
Lot #s: L400077, exp: 8/31/2025; L400113, exp.: 9/30/2025; L400372, L400373, exp.: 3/31/2026; L400374, exp.: 4/30/2026.

## Class II Drugs Event

**Event ID:**
97523

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
09/02/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/10/2025

**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:**
USA Nationwide.

## Associated Products

**Product Description:**
Sulfamethoxazole and Trimethoprim, USP, 800 mg/160 mg, Double Strength, 100 Tablets unit dose blister packs (10x10) per carton, Rx only, Packaged and Distributed by: Major Pharmaceuticals, Indianapolis, IN 46268 USA, NDC 0904-2725-61

**Product Quantity:**
N/A

**Reason for Recall:**
Presence of foreign substance; identified as a microorganism.

**Recall Number:**
D-0624-2025

**Code Information:**
Lot # N02309, Exp 03/31/2027

**Product Description:**
Sulfamethoxazole and Trimethoprim, USP, 800 mg/160 mg, Double Strength, 10 Tablets unit dose blister pack (10x1) per bag, Rx only, Distributed by Cardinal Health, Dublin, OH 43017, NDC 55154-7895-0 (Outer Bag) containing NDC 0904-2725-61 (Inner blisters).

**Product Quantity:**
N/A

**Reason for Recall:**
Presence of foreign substance; identified as a microorganism.

**Recall Number:**
D-0625-2025

**Code Information:**
Bag: N02309A and N02309B, Exp Date: 03/31/2027; Inner blister: Lot # N02309, Exp Date: 03/31/2027

## Class II Drugs Event

**Event ID:**
97534

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
09/03/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/10/2025

**Initial Firm Notification of Consignee or Public:**
N/A

**Recalling Firm:**
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 10 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534. NDC: 70710-1129-1

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0630-2025

**Code Information:**
Lot #: Z403012, Exp Date 30-04-26; Z406657, Exp Date 30-11-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 10 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Manufactured for: Northstar Rx LLC Memphis, TN 38141. NDC: 16714-047-01

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0631-2025

**Code Information:**
Lot#: Z403011, Exp Date 30-04-26; Z407335, Exp Date 30-11-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 25 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534. NDC: 70710-1130-1

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0632-2025

**Code Information:**
Lot #: Z305060, Z305061, Exp Date 31-08-25; Z306323, Exp Date 30-11-25; Z401153, Exp Date 28-02-26; Z403015, Z403016, Exp Date 30-04-26; Z405591, Exp Date 30-09-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 25 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Manufactured for: Northstar Rx LLC Memphis, TN 38141. NDC: 16714-048-01

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0633-2025

**Code Information:**
Lot #: Z305062, exp 31-08-25; Z306324, Exp Date 30-11-25; Z401151, Z401152, Exp Date 28-02-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 50 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534. NDC: 70710-1131-1

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0634-2025

**Code Information:**
Lot #: Z306327, Exp Date 30-11-25; Z306748, Exp Date 30-11-25; Z401154, Exp Date 28-02-26; Z403738, Exp Date 31-05-26; Z405645, Exp Date 30-09-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 50 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Manufactured for: Northstar Rx LLC Memphis, TN 38141. NDC: 16714-049-01

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0635-2025

**Code Information:**
Lot #: Z306326, Exp Date 30-11-25; Z401155, Exp Date 28-02-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 100 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534. NDC: 70710-1132-1

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0636-2025

**Code Information:**
Lot #: Z305079, Z305080, Exp Date 30-09-25; Z305454, Z305455, Z305457, Z400492, Z400493, Z400494, Exp Date 31-12-25; Z401158, Z401725, Z401726, Exp. Date 28-02-26; Z404118, Z404119, Z404120, Exp Date 30-06-26; Z405648, Exp Date 30-09-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 100 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Manufactured for: Northstar Rx LLC Memphis, TN 38141. NDC: 16714-050-01

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0637-2025

**Code Information:**
Lot #: Z305456, Exp Date 31-10-25; Z401156, Exp Date 28-02-26; Z407306, Exp Date 30-11-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 200 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534. NDC: 70710-1133-1

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0638-2025

**Code Information:**
Lot #: Z305083, Z305084, Z305468, Z305469, Z305470, Exp Date 30-09-25; Z401163, Z401165, Exp Date 28-02-26; Z402217, Z402218, Exp Date 31-03-26; Z405518, Z405520, Exp Date 31-08-26; Z406235, Exp Date 31-10-26

**Product Description:**
Chlorpromazine Hydrochloride Tablets, USP, 200 mg, 100-count bottle, Rx only, Manufactured By: Zydus Lifesciences Ltd., Baddi, India; Manufactured for: Northstar Rx LLC Memphis, TN 38141. NDC: 16714-051-01

**Product Quantity:**
N/A

**Reason for Recall:**
CGMP Deviations: presence of N-Nitroso Desmethyl Chlorpromazine above the recommended acceptable intake limit

**Recall Number:**
D-0639-2025

**Code Information:**
Lot #: Z305085, Exp Date 30-09-25; Z401166, Z401167, Exp Date 28-02-26

## Class II Drugs Event

**Event ID:**
97548

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**
N/A

**Recall Initiation Date:**
08/25/2025

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
09/11/2025

**Initial Firm Notification of Consignee or Public:**
E-Mail

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

**Distribution Pattern:**
USA Nationwide

## Associated Products

**Product Description:**
chloroproMAZINE Hydrochloride Tablets, USP, 50 mg, 50 Tablets (5x10) unit dose carton, Rx only, Manufactured for: AvKare, Pulaski, TN, 38478, NDC 50268-164-15

**Product Quantity:**
1512 cartons

**Reason for Recall:**
Presence of a foreign substance.

**Recall Number:**
D-0643-2025

**Code Information:**
Lot # 46824, Exp 9/30/25; 47171, Exp 12/31/25

**Product Description:**
chloroproMAZINE Hydrochloride Tablets, USP, 100 mg, 50 Tablets (5x10) unit dose carton, Rx only, Manufactured for: AvKare, Pulaski, TN, 38478, NDC 50268-165-15

**Product Quantity:**
2003 cartons

**Reason for Recall:**
Presence of a foreign substance.

**Recall Number:**
D-0644-2025

**Code Information:**
Lot # 47089, Exp 12/31/25; 47604, Exp 03/31/26