Enforcement Report - Week of January 14, 2026

Class I Drugs Event

Event ID:
98095

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/12/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/15/2026

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

Recalling Firm:
Medinatura New Mexico, inc.
10421 Research Rd Se
Albuquerque, NM 87123-3423
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
ReBoost Nasal Spray, 0.68 fl. oz. (20 mL) bottles, Distributed by: MediNatura, 10421 Research Rd., SE, Albuquerque, NM 87123, NDC 62795-4005-9, UPC 787647101863

Product Quantity:
N/A

Reason for Recall:
Microbial Contamination of Non-Sterile Products: The products have been found to contain yeast/mold and microbial contamination identified as Achromobacter.

Recall Number:
D-0288-2026

Code Information:
All lots within expiry.

Product Description:
ClearLife Allergy Nasal Spray, Extra Strength, 0.68 fl. oz. (20 mL) bottles, Distributed by: MediNatura, 10421 Research Rd., SE, Albuquerque, NM 87123, NDC 62795-4006-9, UPC 787647101887

Product Quantity:
N/A

Reason for Recall:
Microbial Contamination of Non-Sterile Products: The products have been found to contain yeast/mold and microbial contamination identified as Achromobacter.

Recall Number:
D-0289-2026

Code Information:
All lots within expiry.

Class II Drugs Event

Event ID:
98131

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/08/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2026

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Signature Formulations, LLC
5446 W Roosevelt St Ste 101
Phoenix, AZ 85043-2729
United States

Distribution Pattern:
AZ only

Associated Products

Product Description:
ORL Kids Mouthwash, Bubblegum Flavor, 16.9 oz. (500ml) per bottle, ORL Labs, LLC, Scottsdale, Arizona USA

Product Quantity:
570 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0252-2026

Code Information:
Lot #: 250505P9, Exp. Date 05/27

Product Description:
ORL Kids Natural Toothpaste, Bubblegum Flavor, 4 oz (120ml), ORL Labs, LLC, Scottsdale, Arizona USA

Product Quantity:
1,458 containers

Reason for Recall:
cGMP Deviations

Recall Number:
D-0253-2026

Code Information:
Lot #: 250520P4, Exp. Date 05/27

Class II Drugs Event

Event ID:
98136

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/16/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2026

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
SpecGx, LLC
385 Marshall Ave
Webster Groves, MO 63119-1831
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Oxycodone and Acetaminophen CII Tablets USP, 10mg/325 mg, 100 tablets, Rx only, SpecGx LLC, Webster Groves, MO 63119, NDC 0406-0523-01.

Product Quantity:
287,988 Bottles.

Reason for Recall:
Failed Tablet/Capsule Specification: There is a potential for the imprint to be missing on tablets.

Recall Number:
D-0254-2026

Code Information:
Lot: 0523J23904, expires: 05/2027; 0523J24426, 0523J24427, expires: 06/2027.

Product Description:
Oxycodone and Acetaminophen CII Tablets USP, 7.5 mg/325 mg, 100 tablets, Rx only, SpecGx LLC, Webster Groves, MO 63119, NDC 0406-0522-01. Case label: SpecGx LLC, NDC 0406052201, Exp. 2027/03, Lot: 0522J23493

Product Quantity:
74,544 bottles

Reason for Recall:
Failed Tablet/Capsule Specification: There is a potential for the imprint to be missing on tablets.

Recall Number:
D-0255-2026

Code Information:
Lot: 0522J23493, expires: 03/2027.

Class II Drugs Event

Event ID:
98181

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/18/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
U.S Nationwide

Associated Products

Product Description:
Dexamethasone Moxifloxacin, 1 mg/mL and 5 mg/mL, 1 mL Intraocular Injection, Rx only, Imprimis NJOF, LLC, Ledgewood, NJ 07852, NDC 71384-512-0.1

Product Quantity:
778 boxes of 15,540 pre-filled syringes

Reason for Recall:
Presence of particulate matter - Glass like particles.

Recall Number:
D-0249-2026

Code Information:
Lot: 25MAY051, Expires: 06/26/2026; 25AUG003, Expires:08/07/2026

Product Description:
Dexamethasone Moxifloxacin Ketorolac, 1 mg/mL, 0.5 mg/mL, 0.4 mg/mL) Single-Use Intraocular Injection, Imprimis NJOF, LLC., 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852, NDC 71384-513-01.

Product Quantity:
596 boxes of 11,920 pre-filled syringes

Reason for Recall:
Presence of particulate matter - Glass like particles.

Recall Number:
D-0250-2026

Code Information:
Lot: 25APR001A, 25APR001B, Expires: 04/03/2026.

Product Description:
Tri-Moxi+¿ (Triamcinolone 9mg/0.6mL, Moxifloxacin 0.6 mg/ 0.6 mL) Single-Use Intraocular Injection, Imprimis NJOF, LLC., 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852. NDC 71384-746-06.

Product Quantity:
314 boxes of 6,280 pre-filled syringes

Reason for Recall:
Presence of particulate matter - Glass like particles.

Recall Number:
D-0251-2026

Code Information:
Lot: 25JAN033A, 25JAN033B, Expires: 02/12/2026.

Class II Drugs Event

Event ID:
98246

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2026

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:
Rosuvastatin Tablets, USP, 10 mg, Rx Only, 50 Tablets (5 x 10) Unit Dose per carton, Manufactured for: AvKARE, Pulaski, TN 38478. NDC: 50268-709-15

Product Quantity:
7,991 5x10 cartons

Reason for Recall:
Out of specification for dissolution.

Recall Number:
D-0292-2026

Code Information:
Lot #49124, Exp Date 12/31/2026

Class III Drugs Event

Event ID:
98119

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/16/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2026

Initial Firm Notification of Consignee or Public:
N/A

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

Distribution Pattern:
US Nationwide and PR.

Associated Products

Product Description:
Fesoterodine Fumarate, Extended-release Tablets, 8 mg, 30 Tablets, Rx only, Manufactured by: Alembic Pharmaceuticals Limited, Panelav 389350, Gujarat, India, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, NDC 62332-176-30

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications: Due to levels of 'Diester Impurity' exceeding the specification limit.

Recall Number:
D-0248-2026

Code Information:
Lot# 2405003360, Exp Date: Jan 31, 2026