Enforcement Report - Week of January 8, 2025

Class I Drugs Event

Event ID:
96001

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
GNMart LLC
7 Sawmill Ln
Dover Plains, NY 12522-6086
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
FORCE FOREVER 400mg Tablets, Huesos y articulaciones sin dolor, SUPLEMENTO ALIMENTICIO, 60-count bottles

Product Quantity:
374 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA. FDA analysis found the product to be tainted with Diclofenac and Dexamethasone.

Recall Number:
D-0170-2025

Code Information:
All lots, Exp. Date: 03/27/2030

Class II Drugs Event

Event ID:
95892

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/30/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore, MD 21202-6174
United States

Distribution Pattern:
One US distributor in Ohio.

Associated Products

Product Description:
Levothyroxine Sodium Tablets, Lupin, 75 mcg (0.075mg), 1000 Tablets, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited, Pithampur (M.P)- 454 775 INDIA, NDC# 68180-967-03

Product Quantity:
480 1000-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specifications result observed in the drug substance for impurity test during 3-month long term stability study.

Recall Number:
D-0167-2025

Code Information:
Lot# LA01276, Exp Date: 07/2026

Class II Drugs Event

Event ID:
95919

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/31/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nitrofurantoin Capsules, USP, 100 mg, 50 Capsules (5 x 10) Unit Dose per carton, Rx Only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478. NDC#: 50268-625-15.

Product Quantity:
1016 50-count cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0168-2025

Code Information:
Lot # 47101; Exp. 02/2026

Class II Drugs Event

Event ID:
95930

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:

Voluntary / Mandated:

12/10/2024

Center Classification Date:
01/02/2025

Recalling Firm:
VIONA PHARMACEUTICALS INC
20 Commerce Dr Ste 340
Cranford, NJ 07016-3617
United States

Distribution Pattern:
US Nationwide

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Dapsone Gel 7.5%, 60 g, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahemedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-02. packaged in an Airless pump pack

Product Quantity:
23304 packs

Reason for Recall:
Crystallization

Recall Number:
D-0171-2025

Code Information:
Lots T400513, Exp Date 02/2026; T400807, Exp Date 03/2026; T401152, Exp Date 06/2026; T401303, Exp Date 07/2026; T401304, Exp Date 07/2026; T401399, Exp Date 07/2026 & T401696 Exp Date 08/2026.

Product Description:
Dapsone Gel 7.5%, 90 g, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-03. packaged in an Airless pump pack

Product Quantity:
2760 packs

Reason for Recall:
Crystallization

Recall Number:
D-0172-2025

Code Information:
Lots T400514, Exp Date 02/2026 & T400808, Exp Date 03/2026

Class II Drugs Event

Event ID:
95993

Status:
Ongoing

Recall Initiation Date:
12/19/2024

Center Classification Date:
01/02/2025

Recalling Firm:
Hikma Injectables USA Inc
36 Stults Rd
Dayton, NJ 08810-1540
United States

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
ketamine inj 50 mg per 1 mL, Rx Only, 1 mL fill in a 3mL pre-filled syringe, For IV or IM Use, Hikma Injectables USA Inc., 36 Stults Road, Dayton, NJ 08810, This is a Compounded Drug. Hospital/Office Use Only. NDC 63037-137-25

Product Quantity:
1,800 syringes

Reason for Recall:
Lack of Assurance of Sterility: The tamper-evident seal on several of the syringes are not attached upon receipt of shipment.

Recall Number:
D-0173-2025

Code Information:
Lot number: 242560008D, Use by Date 01/15/2025; 242970002D, Use by Date 02/25/2025

Product Description:
phenylephrine in 0.9% Sodium Chloride Inj, 1mg per 10 mL (100 mcg/mL), Rx only, Hikma Injectables USA Inc., 36 Stults Road, Dayton, NJ 08810, NDC 63037-173-25

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility: The tamper-evident seal on several of the syringes are not attached upon receipt of shipment.

Recall Number:
D-0174-2025

Code Information:
Lot number: 243120003D, Use by Date: 03/11/2025

Class III Drugs Event

Event ID:
95997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/16/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/31/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SOMERSET THERAPEUTICS LLC
300 Franklin Square Dr
Somerset, NJ 08873-4187
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Atropine Sulfate Ophthalmic Solution, USP 1%, 5 mL bottles, Rx only, Manufactured for: Somerset Therapeutics, LLC. Somerset, NJ 08873, NDC 70069-716-01

Product Quantity:
5,870 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0169-2025

Code Information:
Lot #: A240211, Exp. Date April 2026

Class III Drugs Event

Event ID:
96032

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/18/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/02/2025

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Carboxymethylcellulose Sodium Ophthalmic Solution 0.5% Moisturizing Lubricant Eye Drops, 0.5 FL OZ (15 mL) bottles, Distributed by: AvKARE, Pulaski, TN, 38478, NDC 50268-068-15.

Product Quantity:
16,677 cartons

Reason for Recall:
LABELING: LABEL MIX-UP

Recall Number:
D-0175-2025

Code Information:
Lot #: 0160, Exp. Date April 26 2026

Product Description:
Polyvinyl Alcohol Ophthalmic Solution 1.4%, Moisturizing Lubricant Eye Drops, 0.5 FL OZ (15 mL) bottles, Distributed by AvKARE, Pulaski, TN 38478, www.avkare.com, NDC 50268-678-15

Product Quantity:
0

Reason for Recall:
LABELING: LABEL MIX-UP

Recall Number:
D-0176-2025

Code Information:
Lot #: 0160, Exp. Date April 26 2026