Enforcement Report - Week of November 13, 2024

Class I Drugs Event

Event ID:
95503

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/07/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Staska Pharmaceuticals, Inc.
742 Evergreen Dr
Bennet, NE 68317-2365
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Ascorbic Acid Inj. Solution, 25,000mg/50mL (500mg/mL), 50mL single use vial, Rx only, Staska Pharmaceuticals, 742 Evergreen Drive, Bennet, NE 68317

Product Quantity:
4773 vials

Reason for Recall:
Presence of Particulate Matter: Presence of glass particulates.

Recall Number:
D-0040-2025

Code Information:
Lot #SP2400058, Exp 12/31/2024

Class II Drugs Event

Event ID:
95588

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/04/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Morphine Sulfate Extended-Release Tablets 15 mg, 100-count per bottle, Rx Only, Manufactured by Mayne Pharma, Greenville, NC 27834, NDC 51862-185-01.

Product Quantity:
2,040 100-count bottles

Reason for Recall:
Failed Impurities/Degradation Specification

Recall Number:
D-0036-2025

Code Information:
Lot# FG14062, Exp 10/31/2025

Product Description:
Morphine Sulfate Extended-Release Tablets 30 mg, 100-count bottles, Rx Only, Manufactured by Mayne Pharma, Greenville, NC 27834, NDC 51862-186-01.

Product Quantity:
532 100-count bottles

Reason for Recall:
Failed Impurities/Degradation Specification

Recall Number:
D-0037-2025

Code Information:
Lot# FG13996, Exp 09/30/2025

Class II Drugs Event

Event ID:
95618

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
08/09/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/07/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville, GA 30534-6828
United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Ibuprofen 800mg, Generic for: Motrin, Each tablet contains: Ibuprofen, USP 800 mg, Packaged and Distributed by: DIRECT Rx, Dawsonville, GA 30534, Mfg By: Dr. Reddy's Laboratories LA, LLC, Shreveport, LA 71106, a) NDC 61919-0621-15 (15 count bottles), b) NDC 61919-0621-30 (30 count bottles, c) NDC 61919-0621-40 (40 count bottles), d) NDC 61919-0621-60 (60 count bottles), e) NDC 61919-0621-90 (90 count bottles), f) NDC: 61919-0621-100 and NDC: 61919-0621-71 (100 count bottles), g) NDC 61919-0621-72 (120 count bottles).

Product Quantity:
1410 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Product failed impurity specifications at the 18-month stability testing.

Recall Number:
D-0041-2025

Code Information:
Lot #s: a) 02FE2414, Exp 11/30/26. b) 18JU2407, Exp 11/30/26; 27JY2316, Exp 02/28/27; 13SE2317, 13OC2312, 23AU2307, Exp 03/31/27. c) 25SE2308, Exp 03/31/27. d) 29MA2313, 23MA2315, Exp 12/31/26; 25MY2304, Exp 01/31/27; 26JU2313, 27JY2314, Exp 02/28/27. e) 27SE2322, 30OC2304, 12OC2301, Exp 03/31/27. f) 11SE2322, 02FE2419, 23JA2405, 10JA2426, 17MY2416, 05DE2312, 24OC2321, 05FE2433, 20MA2418, 29NO2317, Exp 11/30/26. g) 31MA2308, Exp 12/31/26; 25SE2305, Exp 03/31/27.

Class II Drugs Event

Event ID:
95648

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
FDC Limited
B-8 MIDC Industrial Area Waluj District
Aurangabad, Maharashtra State
India

Distribution Pattern:
Distributed to one Us Distributor in NJ.

Associated Products

Product Description:
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 5mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-514-05.

Product Quantity:
155,232 bottles

Reason for Recall:
Defective Container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle

Recall Number:
D-0035-2025

Code Information:
Lot #: 083L051, Exp. Date: 11/2025

Class II Drugs Event

Event ID:
95650

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/05/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Dapsone Gel 7.5%, 60 gram pump, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-02.

Product Quantity:
6048 pumps

Reason for Recall:
Crystallization

Recall Number:
D-0038-2025

Code Information:
Lots T401151, Exp, 06/30/2026; T400806, Exp 03/31/2026

Class II Drugs Event

Event ID:
95664

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/30/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield, IL 60015-4625
United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Regadenoson Injection, 0.4 mg/5 mL (0.08 mg/mL), 5mL Single-Dose Pre-filled Syringe, Rx only, Manufactured by: Baxter Pharmaceutical Solutions, LLC, Bloomington, IN 47403; Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015. NDC: 36000-364-01

Product Quantity:
60,594 units

Reason for Recall:
Labeling: Missing Label

Recall Number:
D-0039-2025

Code Information:
Lot #: 945169, Exp. Date 9/25/2025; 945170, Exp. Date 10/24/2025

Class III Drugs Event

Event ID:
95430

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
09/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denison Pharmaceuticals, LLC
1 Powder Hill Rd
Lincoln, RI 02865-4407
United States

Distribution Pattern:
Product was distributed to two accounts that may have distributed the product further to the Retail Level.

Associated Products

Product Description:
Adult Cough and Chest Congestion (Dextromethorphan HBr USP 20 mg, Guaifenesin USP 400mg), packaged in 4 oz bottles further package in cartons, Distributed by: Genexa Inc., Alanta, GA, 30318, NDC-69676-0077-9, UPC Code # 850015736155

Product Quantity:
72,648 bottles

Reason for Recall:
Crystallization: Lack of uniformity - a change in texture, chunky, grainy, and small crystal substances inside the bottles.

Recall Number:
D-0033-2025

Code Information:
Lot# 0104V, Exp 07/2025; 0106V, Exp 09/2024

Product Description:
Kids' Cough and Chest Congestion (Dextromethorphan HBr, USP 5mg/ Guaifenesin, USP 100 mg), packaged in 4 oz bottles further packaged in cartons, Distributed by: Genexa Inc., Alanta, GA, 30318, NDC-69676-0077-9, UPC Code# 850015736018

Product Quantity:
105,048 bottles

Reason for Recall:
Crystallization: Lack of uniformity - a change in texture, chunky, grainy, and small crystal substances inside the bottles.

Recall Number:
D-0034-2025

Code Information:
Lot#: 0813V, Exp 06/2025; 0103V, Exp 03/2025