Enforcement Report - Week of February 28, 2024

Class I Drugs Event

Event ID:
93808

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Neptune Resources, LLC
1324 W 12th St Fl 5
Kansas City MO United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Neptune's Fix, Tianeptine Elixir, Fast Acting, 0.338 fl oz (10 mL) bottle, Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.

Product Quantity:
1,000,000 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.

Recall Number:
D-0333-2024

Code Information:
All lots

Product Description:
Neptune's Fix, Tianeptine Extra Strength Elixir, 0.338 fl oz (10 mL) bottle, Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.

Product Quantity:
117,000 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.

Recall Number:
D-0334-2024

Code Information:
All lots

Product Description:
Neptune's Fix, Tianeptine Tablets Extended Relief, Twenty Tablets per Box, Wide Awake, 3000 mg (150 mg Per Tablet), Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.

Product Quantity:
4,932 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.

Recall Number:
D-0335-2024

Code Information:
All lots

Class I Drugs Event

Event ID:
93928

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company
660 White Plains Rd Ste 250
Tarrytown NY United States

Distribution Pattern:
Product was distributed nationwide and to 4 foreign accounts. Guaynabo, Puerto Rico; Georgetown, Guyana; Baghdad, Iraq; Accra, Ghana.

Associated Products

Product Description:
TING 1% Tolnaftate Athlete's Foot Spray Antifungal Spray Liquid, NET WT 4.5 oz. (128 g) cans, Distributed by: Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company, Tarrytown, NY 10591 UPC 3 63736 81961 3

Product Quantity:
59,644 cans

Reason for Recall:
Chemical Contamination; presence of benzene.

Recall Number:
D-0346-2024

Code Information:
Lot # 0H50545, Exp. date 07/31/24; 1G50645, Exp. date 06/30/25

Class I Drugs Event

Event ID:
93941

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Today The World
1954 NE Glisan St # 405
Portland OR United States

Distribution Pattern:
Product distributed nationwide within the United States.

Associated Products

Product Description:
Sustain Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by VSD Productions, Inc. Las Vegas, Nevada

Product Quantity:
7000 boxes

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found this product to be tainted with undeclared tadalafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this drug an unapproved drug.

Recall Number:
D-0343-2024

Code Information:
Lot #: BTH:230551, Exp. Date 12.05.2026; BTH:230571, Exp. Date 14.05.2026

Product Description:
SCHWINNNG Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by: Today the World LLC, Vancouver, WA 98683

Product Quantity:
11500 boxes

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared nortadalafil, an ingredient found in FDA approved product for the treatment of male sexual enhancement, making this drug an unapproved drug.

Recall Number:
D-0344-2024

Code Information:
Lot #: 2108, Exp. Date 10/31/2024.

Product Description:
Arize Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by: Natural Herbal Remedies, LLC, Cheyenne, WY 82001, www.getarize.com

Product Quantity:
5500 boxes

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared nortadalafil, an ingredient found in FDA approved product for the treatment of male sexual enhancement, making this drug an unapproved drug.

Recall Number:
D-0345-2024

Code Information:
Lot #: 2107, Exp. Date 10/31/2024.

Class II Drugs Event

Event ID:
93816

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/16/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/20/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC

339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fosfomycin Tromethamine Granules for Oral Solution, (equivalent to 3 grams of fosfomycin), single-dose sachet, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC. Parsippany, NJ 07054. NDC 67877-749-57

Product Quantity:
71,244 sachets

Reason for Recall:
Failed Impurities/Degradation Specification: Out of specification for organic impurities

Recall Number:
D-0339-2024

Code Information:
lOTS #: 22121458, 22121459, 22121460, 22121461, 22121462, 22121463, 22121464, Exp 4/2024; 22121176, 22121407, 22121465, Exp 3/2024; 22121761, 22121762, 22121763, 22121764, 22121766, 22121968, 22121969, Exp 5/2024.

Class II Drugs Event

Event ID:
93839

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Henry Schein Inc. and Glove Club HSI Gloves Inc.
135 Duryea Rd
Melville NY United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Adrenalin (epinephrine) Injection 1mg/mL, 1mL single dose vial, Rx only, Packaged By: Henry Schein, Inc., 80 Summit View Lane, Bastian, VA 24314, Original NDC 42023-159-25 Repack NDC 0404-9810-01

Product Quantity:
1,099 Single Dose Vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date. The expiration date listed on the Repack Pouch Label is incorrect.

Recall Number:
D-0342-2024

Code Information:
Original Lot # 64103, exp. date 11/24 Repackaged Lot # 39747, exp. date 01/26

Class II Drugs Event

Event ID:
93843

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Norepinephrine Bitartrate in 5% Dextrose Injection, 8 mg/ 250 mL (32 mcg/mL), For Intravenous Infusion Only, 250 mL vial, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015. Made in Ireland. NDC: 0338-0108-20

Product Quantity:
13,000 bags

Reason for Recall:
Incorrect product concentration on the overwrap label: The overwrap label incorrectly identified the product strength as 4 mg / 250 mL; however, the primary bag label correctly identified the product strength as 8 mg / 250 mL.

Recall Number:
D-0336-2024

Code Information:
Lot 23I21G64; Exp. 07/31/2024

Class II Drugs Event

Event ID:
93869

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Bestco LLC
288 Mazeppa Rd
Mooresville NC United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
CVS Health Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 160 drops per bag, item number 20001089, Bestco, 288 Mazeppa Road, Mooresville, NC 28115

Product Quantity:

78 cases/18 packs each

Reason for Recall:
CGMP Deviations: Potential Glass and Silicone particulates in product

Recall Number:
D-0328-2024

Code Information:
100042059, Exp 12/31/2026

Product Description:
Meijer Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 200 drops per bag, item number 20000345, Bestco, 288 Mazeppa Road, Mooresville, NC 28115

Product Quantity:
16 cases/4 pack each

Reason for Recall:
CGMP Deviations: Potential Glass and Silicone particulates in product

Recall Number:
D-0329-2024

Code Information:
100042236, Exp 12/31/2026

Product Description:
Kroger Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 200 drops per bag, item number 20000064, Bestco, 288 Mazeppa Road, Mooresville, NC 28115

Product Quantity:
21 cases/4 pack each

Reason for Recall:
CGMP Deviations: Potential Glass and Silicone particulates in product

Recall Number:
D-0330-2024

Code Information:
100042238, Exp 12/31/2026

Product Description:
Family Wellness Cherry Cough Drops Menthol cough suppressant/Oral Anesthetic, 80 drops per bag, item number 20001187, Bestco, 288 Mazeppa Road, Mooresville, NC 28115

Product Quantity:
46 cases/6 pack each

Reason for Recall:
CGMP Deviations: Potential Glass and Silicone particulates in product

Recall Number:
D-0331-2024

Code Information:
100042290, Exp 12/31/2026

Product Description:
Equate Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, a) 30 drops per bag, item number 20000462, b) 160 drops per bag, item number 20000463, Bestco, 288 Mazeppa Road, Mooresville, NC 28115

Product Quantity:
a) 1597 cases/ 12 pack each b) 73 cases/4 pack each

Reason for Recall:
CGMP Deviations: Potential Glass and Silicone particulates in product

Recall Number:
D-0332-2024

Code Information:
a) 100041954, Exp 12/31/2026; b) 100042048, 100042060, Exp 12/31/2026

Class II Drugs Event

Event ID:
93880

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alpha Aromatics
294 Alpha Dr
Pittsburgh PA United States

Distribution Pattern:
Product was distributed to two accounts in NC and MI

Associated Products

Product Description:
Pure Care Foaming Mint Hand Sanitizer 62%, Distributed by: Air Scent International, 290 Alpha Drive, RIDC Industrial Park, Pittsburg, PA 15238 USA, www.airscent.com, NDC 75009-562.

Product Quantity:
676 gallons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0338-2024

Code Information:
Lot # 2022-012884 Lot # 2023-002020 Lot # 2023-003532 Lot # 2023-003761

Class II Drugs Event

Event ID:
93934

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
OH, IL, NJ

Associated Products

Product Description:
Voriconazole for Oral Suspension, 40mg/mL, Orange-Flavored, 49g/75mL when reconstituted. Mixing Directions: Tap the bottle to release the powder. Add 50mL of water to the bottle and shake vigorously for 1 minute. Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873. Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202. NDC: 43386-038-60.

Product Quantity:

Reason for Recall:
Labeling: Incorrect or Missing Package Insert

Recall Number:
D-0337-2024

Code Information:
Lot#: S200756; Exp. 10/2024 Lot#: S300218; Exp. 04/2025 Lot#: S300633; Exp. 09/2025

Class II Drugs Event

Event ID:
93945

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mallinckrodt Hospital Products Inc.
440 Us Highway 22 Ste 302
Bridgewater NJ United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Acthar Gel (repository corticotropin injection) 400 USP units/5mL (80 USP units/mL), 5mL multiple-dose vial, Rx only, Mfd. for: Mallinckrodt ARD LLC, Bridgewater, NJ 08807, NDC 63004-8710-1

Product Quantity:
8 vials involved in recall (16,479 vials distributed)

Reason for Recall:
cGMP deviations: Temperature excursion due to shipping delay from manufacturer to distributor. Affected distributor has been notified.

Recall Number:
D-0340-2024

Code Information:
Lot #: 1564-103, Exp 9/30/2024

Product Description:
Terlivaz (terlipressin for injection), 0.85mg/vial, Single-Dose Vial, Rx only, Distributed by: Mallinckrodt Hospital Products Inc., Bridgewater, NJ 08807, USA, NDC 43825-200-01

Product Quantity:
421 vials involved in this recall (2,448 vials distributed)

Reason for Recall:
cGMP deviations: Temperature excursion due to shipping delay from manufacturer to distributor. Affected distributor has been notified.

Recall Number:
D-0341-2024

Code Information:
Lot #: 22TRP01-F2, Exp 6/30/2024

Class II Drugs Event

Event ID:
93959

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Oseltamivir Phosphate for Oral Suspension 6mg/ml, 60 mL (reconstituted) bottle, RX only, Distributed by Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC# 69238-1273-6

Product Quantity:
46,037 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-specification test results.

Recall Number:
D-0327-2024

Code Information:
Lot # BF22722A, Exp. 08/31/2024; BJ15122A, Exp. 09/30/2024

Class II Drugs Event

Event ID:
93974

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fluticasone Propionate Nasal Spray USP 50mcg, 120 Metered Sprays - 16 g net fill, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9, Manufactured for: Apotex Corp Weston, FL 33326. NDC 60505-0829-1

Product Quantity:
292,752 bottles

Reason for Recall:
Potential presence of Burkholderia cepacia complex (BCC)

Recall Number:
D-0326-2024

Code Information:
Lot number # TX5274 Exp. 09/30/2026

Class II Drugs Event

Event ID:
93975

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Micro Labs Limited
Plot# S - 155 & N1 Phase Iii & Phase Iv; Verna Ind Estate Road
Verna India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Clobazam Tablets 10mg, 100-count bottle, Rx Only, Manufactured by: Micro Labs Limited Goa-403 722, India. Manufactured for: Micro Labs USA, Inc. Somerset, NJ 08873. NDC 42571-315-01

Product Quantity:
24,768 bottles

Reason for Recall:
CGMP Deviations: Out of specification for residual solvents.

Recall Number:
D-0348-2024

Code Information:
ZOAG043

Class II Drugs Event

Event ID:
94023

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
MCKESSON CORPORATION
6555 NORTH STATE HIGHWA
IRVING TX United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
CABTREO (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1%, Not for Oral, Ophthalmic or Intravaginal Use, Rx Only, Net Wt. 50g, Distributed by Bausch Health US, LLC Bridgewater, NJ 08807 USA, Manufactured by: Bausch Health Companies, Inc. Laval Quebec H7L 448, Canada, NDC 0187-0006-25.

Product Quantity:
42 units

Reason for Recall:
CGMP Deviations: Product was stored outside labeled storage temperature requirements. Product was exposed to controlled room temperature environment instead of remaining refrigerated.

Recall Number:
D-0347-2024

Code Information:
Lot: 7001796, Exp 05/31/2025