Enforcement Report - Week of April 24, 2024

Class I Drugs Event

Event ID:
94262

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2024

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:
Vancomycin Hydrochloride for Oral Solution, USP, 250 mg per 5 mL, packaged as (a) 80 mL bottle, NDC 69238-2261-3; (b) 150 mL bottle, NDC 69238-2261-7; (c)300 mL bottle, NDC 69238-2261-5; Rx only, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807

Product Quantity:
821 bottles

Reason for Recall:
Superpotent Drug: Due to overfilling of drug powder

Recall Number:
D-0442-2024

Code Information:
Lot # (a) 22613003A, Exp. date 09/30/2025; (b) 22613004A, 22613005A, Exp. date 09/30/2025; (c) 22613005B, Exp. date 09/30/2025

Class I Drugs Event

Event ID:
94329

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/28/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski TN United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Atovaquone Oral Suspension USP, 750 mg per 5 mL sachets, 20 Units x 5 mL cartons, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 50268-086-12.

Product Quantity:
153 cartons

Reason for Recall:
Microbial contamination of a non-sterile product: potential Bacillus cereus contamination.

Recall Number:
D-0444-2024

Code Information:
Lot: AW0221A Exp. 08/30/2025

Class II Drugs Event

Event ID:
94214

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/17/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Eli Lilly & Company
893 S Delaware St
Indianapolis IN United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Sterile Diluent, HUMALOG U-100 (insulin lispro injection), HUMULIN R U-100 REGULAR (insulin human injection), Insulin Lispro Injection u-100, 10 mL, Use ONLY with Insulins listed on carton, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285. NDC: 0002-0800-01

Product Quantity:
700 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0445-2024

Code Information:
Batch number: D608951C, exp 4/10/2025

Class II Drugs Event

Event ID:
94268

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Specialty Process Labs LLC
1850 E Riverview Dr
Phoenix AZ United States

Distribution Pattern:
U.S. Nationwide.

Associated Products

Product Description:
S.P.Labs, Thyroid, Full Strength, Rx only, For Manufacturing, Processing or Repackaging Use Only, Specialty Process Labs, Phoenix, AZ 85034, NDC 81305-500-01.

Product Quantity:
26 units

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0446-2024

Code Information:
Lot #: H22212-FSV, Exp: 11/21/2024 1.0 kg pack size.

Product Description:
S.P Labs, Thyroid, USP, Rx only, For Manufacturing, Processing or Repackaging Use only, Specialty Process Labs, Phoenix, AZ, NDC #'s a) 81305-100-01, b)81305-100-02, c)81305-100-03

Product Quantity:
217 units

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0447-2024

Code Information:
Lot #: L13152-1XV, Exp: 11/21/2024; a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: B10383-1XV, Exp: 02/14/2025, a)1 kg, b)0.5 kg, c)100g pack sizes. Lot #: B10453-1X, Exp: 02/15/2025, a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: C10803-1X, Exp: 03/23/2025, a)1.00 kg, c)100g pack sizes. Lot #: E11363-1X, Exp: 05/18/2025, a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: K12753-1X, Exp: 10/12/2025, a)1.00 kg pack sizes. Lot #: L13103-1X, Exp: 11/13/2025, a)1 kg, b)0.5 kg, c)100g pack sizes.

Class III Drugs Event

Event ID:
94255

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novitium Pharma LLC
70 Lake Dr
East Windsor NJ United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Digoxin Tablets, USP 62.5 mcg (0.0625 mg), 100-count bottles, Rx Only, Manufactured by: Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, NDC 70954-200-10

Product Quantity:
1,003 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0443-2024

Code Information:
Lot M23011A; Exp. 12/2024

Class III Drugs Event

Event ID:
94365

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/27/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/12/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Esperion
3891 Ranchero Dr Ste 150
Ann Arbor MI United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
NEXLIZET (bempedoic acid and ezetimibe) tablets, 180 mg/10 mg, 30-count bottle, Rx only, Manufactured for: Esperion Therapeutics, Ann Arbor, MI 48108, NDC 72426-818-03

Product Quantity:
3,480 30-count bottles

Reason for Recall:
Failed dissolution specifications: out-of-specification bempedoic acid dissolution at the 0-month timepoint.

Recall Number:
D-0441-2024

Code Information:
Lot #, 1990305, Exp 08-31-2025