Enforcement Report - Week of February 7, 2024

Class I Drugs Event

Event ID:
93710

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood CO United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
FentaNYL citrate PF, 1000 mcg per 100 mL 0.9% Sodium Chloride (10 mcg per mL), Item F3355, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-072-41.

Product Quantity:
8,976 IV bags

Reason for Recall:
Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0277-2024

Code Information:
Lot #: 2331062, Exp. Date: 02/08/2024; 2331224, Exp. Date 03/18/2024; 2331270, Exp. Date 03/28/2024.

Product Description:
FentaNYL citrate PF, 2500 mcg per 250 mL 0.9% Sodium Chloride (10 mcg per mL), Item F3342, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-072-82.

Product Quantity:
13,920 IV bags

Reason for Recall:
Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0278-2024

Code Information:
Lot #: 2330988, Exp. Date 01/31/2024; 2331058, Exp. Date 02/18/2024; 2331150, Exp. Date 03/10/2024; 2331231, Exp. Date 03/24/2024; 2331289, Exp. Date 03/30/2024.

Product Description:
PHENYLephrine HCl 20 mg per 250 mL 0.9% Sodium Chloride (80 mcg per mL), Item F3360, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-148-94.

Product Quantity:
29,016 IV bags

Reason for Recall:

Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0279-2024

Code Information:
Lot #: 2330993, Exp. Date 02/15/2024; 2331010, Exp. Date 02/10/2024; 2331055, Exp. Date 01/18/2024; 2331113, Exp. Date 02/26/2024; 2331181, Exp. Date 03/04/2024; 2331187, Exp. Date 03/23/2024; 2331266, Exp. Date 03/31/2024; 2331343, Exp. Date 04/01/2024; 2331349, Exp. Date 04/23/2024; 2331433, Exp. Date 05/05/2024.

Product Description:
PHENYLephrine HCl 40 mg per 250 mL 0.9% Sodium Chloride (160 mcg per mL), Item F3352, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-150-82.

Product Quantity:
12,564 IV bags

Reason for Recall:
Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0280-2024

Code Information:
Lot #: 2330939, Exp. Date 01/30/2024; 2331032, Exp. Date 02/03/2024; 2331112, Exp. Date 03/19/2024; 2331190, Exp. Date 03/26/2024; 2331429, Exp. Date 04/28/2024.

Product Description:
VANCOmycin HCl PF 1.25g added to 0.9% Sodium Chloride 250 mL IV bag, Item F3206, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-028-68.

Product Quantity:
10,152 IV bags

Reason for Recall:
Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0281-2024

Code Information:
Lot #: 2331184, Exp. Date 02/13/2024; 2331185, Exp. Date 02/10/2024; 2331189, Exp. Date 02/20/2024; 2331191, Exp. Date 02/24/2024; 2331258,Exp. Date 03/03/2024; 2331317, Exp. Date 03/15/2024.

Product Description:
VANCOmycin HCl PF 1.5g added to 0.9% Sodium Chloride 250 mL IV bag, Item F3208, for IV use only; Leiters 13796 Compark Blvd Englewood, CO 80112; NDC 71449-029-68.

Product Quantity:
7,548 IV bags

Reason for Recall:
Superpotent Drug: semi-automated IV bag filling system can malfunction and provide a double dose of drug product to IV bags.

Recall Number:
D-0282-2024

Code Information:
Lot #: 2331140, Exp. Date 02/08/2024; 2331188, Exp. Date 02/15/2024; 2331261, Exp. Date 03/05/2024; 2331287, Exp. Date 03/14/2024.

Class II Drugs Event

Event ID:
93730

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

01/03/2024

Center Classification Date:
01/26/2024

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

Distribution Pattern:
Nationwide in the USA

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Cefixime for Oral Suspension 100mg/5mL, 50 mL bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, Manufactured by:Lupin Limited, Mandideep 462 046 INDIA, NDC 68180-405-01

Product Quantity:
4,608 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0274-2024

Code Information:
Lot #: F304833, Exp 06/2025

Class II Drugs Event

Event ID:
93740

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/08/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/26/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Budesonide Extended-Release Tablets 9mg, 30-count bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314 USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA, NDC 0591-2510-30

Product Quantity:
10,672 30-count bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0275-2024

Code Information:
Lot # 100047273; Exp. 07/2025

Class II Drugs Event

Event ID:
93753

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/30/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to 32 Wholesale/distributor accounts who further distributed the product to 156 distribution sites.

Associated Products

Product Description:
Rifampin Capsules USP 150mg, 30-count bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States, Manufactured Lupin Limited, Aurangabad 431 210 INDIA, NDC 68180-658-06

Product Quantity:
15,576 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0283-2024

Code Information:
A200816 exp 1/2024 A201248 exp 3/2024

Product Description:
Rifampin Capsules USP 300mg, 30-count bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States, Manufactured Lupin Limited, Aurangabad 431 210 INDIA, NDC 68180-659-06

Product Quantity:
165,60 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0284-2024

Code Information:
A200817 exp 1/2024

Class II Drugs Event

Event ID:
93831

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

01/16/2024

Center Classification Date:
01/31/2024

Recalling Firm:
Den-Mat Holdings, LLC
1017 W Central Ave
Lompoc CA United States

Distribution Pattern:
Nationwide in the US

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
OralProCare medicated lip treatment, Net Wt 9.9 g (0.35 oz) tube, Ethyl alcohol 6.0% Antibacterial, Manufactured by: Den-Mat Holdings, LLC, Lompoc, CA, 93436, USA, NDC 59883-500-01, UPC: 3 59883 00000 4.

Product Quantity:
344 tubes

Reason for Recall:
CGMP Deviations: products may not conform to the labeled specifications.

Recall Number:
D-0286-2024

Code Information:
Lot #s: 2319500023, Exp: 01- 12-2024; 2330400002, Exp: 11-02-2024.

Product Description:
Hydrogen Peroxide Oral Rinse, Significantly Reduces Bacteria, Fresh Mint Flavor, Alcohol Free, a)16 fl. oz. (473 mL) bottle, NDC 59883-202-16, UPC 3 59883 00009 7); b) 64 fl. oz. (1.89 L) bottle, NDC 59883-202-64; c) 128 fl. oz. (1 gal) 3.78L bottle, NDC 59883-202-28, UPC 3 59883 00007 3), Manufactured by: Den-Mat Holdings, LLC, Lompoc, CA 93436.

Product Quantity:
10,103 units

Reason for Recall:
CGMP Deviations: products may not conform to the labeled specifications.

Recall Number:
D-0287-2024

Code Information:
Lot #: a) 2214500032, 2216700041, 2301900118, 2312600002, 2204800002, Exp. 02/05/2024; 2306100034, 2322000078, 2322200021 02/22/2024; 2318000026, Exp 02/24/2024; 2323000070, 2324400005, 2323300016, Exp 08/29/2025; 2324800079, Exp 08/30/2025; 2325800008, Exp 09/18/2025; 2328600011, 2328600032, 10/10/2025; 2324800123, Exp 10/11/2025; 2329700005, 2329700090, Exp 10/19/2025; 2330400003, Exp 10/25/2025; 2334100101, Exp 11/13/2025; 2335300019, 2335400038, Exp 12/19/2025. b) 2212200014, Exp 02/22/2024; 2323300017, Exp 08/29/2025; 2324800124, Exp 09/18/2025. c) 2211100001, Exp 02/24/2024; 2330500009, Exp 10/25/2025; 2333200014, Exp12/19/2025.

Class II Drugs Event

Event ID:
93851

Status:
Ongoing

Recall Initiation Date:
01/11/2024

Center Classification Date:
01/30/2024

Recalling Firm:
Amerisource Health Services LLC

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Rifampin Capsules USP, 150 mg, 30 Capsules (3 x 10) unit doses per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-575-21; NDC Unit Dose: 60687-575-11

Product Quantity:
1,568 cartons

Reason for Recall:
Failed Impurities/Degradation Specification.

Recall Number:
D-0285-2024

Code Information:
Lot #: 1008111, Exp. Date 01/31/2024

Not Yet Classified Drugs Event

Event ID:
93786

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Azurity Pharmaceuticals, Inc.
841 Woburn St
Wilmington MA United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Zenzedi (Dextroamphetamine Sulfate) CII Tablets, USP, 30 mg, 30-count bottle, Rx only, Mfd. for: Arbor Pharmaceuticals, LLC., Atlanta, Georgia, 30328, NDC 24338-856-03

Product Quantity:
4,662 bottles

Reason for Recall:
Labeling: Label Mix-up

Recall Number:

Code Information:
Lot # F230169A, Exp. 06/30/2025