Enforcement Report - Week of May 29, 2024

Class I Drugs Event

Event ID:
94522

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/23/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
CO, GA, PA, SD, WA

Associated Products

Product Description:
Phenylephrine in 0.9% Sodium Chloride Injection Preservative Free, 100mcg/mL, 5mL syringe, Rx only, Hikma Injectables USA Inc, 36 Stults Road, Dayton, NJ 08810, NDC 63037-123-25

Product Quantity:
N/A

Reason for Recall:
Labeling: Label mix-up - ephedrine syringes mislabeled as phenylephrine.

Recall Number:
D-0508-2024

Code Information:
Lot #: 240310003D, Exp 6/4/2024

Class II Drugs Event

Event ID:
94452

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2024

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:
Haloperidol decanoate Injection 50mg/mL, packaged in a) 1 mL Single-Dose Vials (NDC 70069-381-01) and b) 10 1mL Single-Dose Vials (NDC 70069-381-10), Rx only, Manufactured for: Somerset Therapeutics, LLC, Hollywood, FL 33024, Made in India.

Product Quantity:
5,578 units

Reason for Recall:
Presence of Foreign Substance: This oil based product may contain trace amounts of water for injection (WFI).

Recall Number:
D-0506-2024

Code Information:
Lot #: a) A230412A, Exp. Date 07/2025; b)A230412B, Exp. Date 07/2025

Class II Drugs Event

Event ID:
94619

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/13/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Regent, Inc.
6610 New Albany Rd E
New Albany, OH 43054-8730
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Vasopressin Injection, USP, 200 Units per 10 mL (20 Units per mL), 10 mL Multiple-Dose Vial, Rx only, For Intravenous Infusion, American Regent, Inc., Shirley, NY 11967, NDC 0517-1030-01

Product Quantity:
2,352 vials

Reason for Recall:
Subpotent product in addition to having out-of-specification results for impurities.

Recall Number:
D-0507-2024

Code Information:
Lot #: 23061L1C0, Exp 1/31/2025

Class II Drugs Event

Event ID:
94621

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Regent, Inc.
6610 New Albany Rd E
New Albany, OH 43054-8730
United States

Distribution Pattern:
UT only

Associated Products

Product Description:
niCARdipine Hydrochloride Injection, USP, 25 mg/10 mL (2.5 mg/mL), 10 x 10 mL Single Dose Vials, Rx Only, For Intravenous Use Only, Mfd for: Civica, Inc., Lehi, UT 84043; Mfd by: American Regent, Inc., New Albany, OH 43054. NDC 72572-470-10

Product Quantity:
4,136 cartons (10 vials in each carton)

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-0503-2024

Code Information:
Lot #: 23087N0C0, Exp. Date 11/2024

Class II Drugs Event

Event ID:
94648

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/10/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim, CA 92807-1801
United States

Distribution Pattern:
Product distributed to CA, FL, OK, KS and CT

Associated Products

Product Description:
Duloxetine Delayed-Release Cap USP 30mg, 30-count bottle, Rx only, Preferred Pharmaceutcals, Inc., NDC 68788-9301-03

Product Quantity:
66 bottles of 30 tablets

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Recall Number:

D-0505-2024

Code Information:
Lot #: J2022G, Exp: 01/01/2025

Class III Drugs Event

Event ID:
94465

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/20/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
TX, PA

Associated Products

Product Description:
Xelpros (latanoprost ophthalmic emulsion) 0.005%, 125mcg/2.5mL, 2.5 mL bottle, Rx only, Manufactured by: Sun Pharmaceutical Ind. Ltd., India., NDC 47335-317-90

Product Quantity:
35,069 bottles

Reason for Recall:
Failed Release Testing: Out of specification for particulate matter test.

Recall Number:
D-0502-2024

Code Information:
Lot #: HAD3383A, Exp 8/31/2024

Class III Drugs Event

Event ID:
94535

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/21/2024

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:
US Nationwide.

Associated Products

Product Description:
Sirolimus Tablets 1mg Tablets 100-count bottle, Rx Only, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-653-01

Product Quantity:
1,176 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0504-2024

Code Information:
Lot H2200493; Exp 6/30/2025