Enforcement Report - Week of March 27, 2024

Class I Drugs Event

Event ID:
93946

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/05/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Super Chill Products
827 6th Ave
New York NY United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Neptune's Fix, Tianeptine Elixir, Fast Acting, 0.338 fl.oz. (10 mL) bottle, Distributed By Superchill Products, 827 6th Avenue, New York, New York 10001.

Product Quantity:
3,573 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-0393-2024

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
94073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Nicardipine Hydrochloride Injection (2.5mg/mL), US, 25mg per 10mL, 10mL Vial, Rx only, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520 NDC 55150-183-10

Product Quantity:
335,940 vials

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

Recall Number:
D-0390-2024

Code Information:
Lot #: 3NC23002, Exp. Date 7/24; 3NC22013, 3NC22014, 3NC22015, 3NC22016, 3NC22017, 3NC22018, Exp. Date 2/24; 3NC22020, Exp. Date 3/24

Product Description:
Nicardipine Hydrochloride Injection, USP 25mg/mL (2.5 mg/mL) 10 mL vials, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520, NDC 55150-183-11

Product Quantity:
43,920 vials

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

Recall Number:
D-0391-2024

Code Information:
Lot #: 3NC22019, Exp. Date 2/24

Class II Drugs Event

Event ID:
94208

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/21/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Infumorph (Preservative-free Morphine Sulfate Sterile Solution), 20 mL ampul, Rx only, Manufactured by Hikma Berkeley Heights, NJ 07922, NDC 0641-6039-01

Product Quantity:
22,644 ampuls

Reason for Recall:
The filter included in the carton has an expiration date that has expired prior to the expiration date of the actual product lot.

Recall Number:
D-0392-2024

Code Information:
Lot #: 052001, 052003, Exp. Date 11/2024; 023012, 023014, Exp. Date 08/2024

Class III Drugs Event

Event ID:
94132

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/15/2024

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Digoxin Tablets, USP 125mcg, (0.125 mg), 1000-count bottle, Rx Only, Manufactured by: Novitium Pharma LLC., 70 Lake Drive, East Windsor, New Jersey 08520, NDC 70954-201-20

Product Quantity:
3,940 1000-count bottles

Reason for Recall:
Cross Contamination with Other Products:(mycophenolate mofetil).

Recall Number:
D-0389-2024

Code Information:
Lot #: M23172A, Exp 01/31/2025