Enforcement Report - Week of January 11, 2023

Class II Drugs Event

Event ID:
91379

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Heparin Sodium 2,000, USP Units, per 1,000 mL (2 USP Units/mL) in 0.9% Sodium Chloride Injection, 1,000 mL bags, a) Case (NDC 0409-7620-59), b) Single Unit (NDC 0409-7620-49), Rx only, Distributed By Hospira, Inc., Lake Forest, IL 60045 USA,

Product Quantity:
62,088 bags

Reason for Recall:
Lack of assurance of sterility: Bags have the potential to leak.

Recall Number:
D-0097-2023

Code Information:
Lot: 5935283, Exp. 12/01/2023

Class II Drugs Event

Event ID:
91406

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2023

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 in the USA

Associated Products

Product Description:
Acyclovir Sodium Injection 1,000 mg per 20 mL* (50 mg/mL); Single Dose 20mL Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd, E. Windsor, NJ 08520; Made in India. NDC 55150-155-20

Product Quantity:
45,250 vials

Reason for Recall:
Presence of Particulate Matter: Customer complaint of dark particles found inside the vial

Recall Number:
D-0095-2023

Code Information:
Lot # AC22004, Expiry: 08/2023

Class III Drugs Event

Event ID:
91412

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Prochlorperazine Maleate Tablets, USP 5mg, 100 tablets, RX Only, Jubilant Cadista Pharmaceuticals, Inc., Salisbury, Maryland 21801, NDC 59746-113-06

Product Quantity:
14,061 bottles

Reason for Recall:
Subpotent Drug: Out of specification for assay at the 18-month stability timepoint.

Recall Number:
D-0096-2023

Code Information:
Lot#: 21P0336, Exp: 04/2023

Not Yet Classified Drugs Event

Event ID:
91378

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Pine Pharmaceuticals, LLC
355 Riverwalk Pkwy
Tonawanda NY United States

Distribution Pattern:
Nationwide to medical facilities.

Associated Products

Product Description:
Epi-Caine, Epinephrine 0.025% Lidocaine HCL 0.75% Solution for Intraocular Injection, 1 ml, Single Dose Vial, Compounded by Pine Pharmaceuticals, 355 Riverwalk Pkwy, Tonawanda, NY 14150. NDC 69194-0948-1

Product Quantity:
11,453 vials

Reason for Recall:
CGMP Deviations: Raw material recalled by repackager, due to discoloration.

Recall Number:

Code Information:
Lot # 62881, Exp 12/25/2022; 62923, Exp 12/26/2022; 63066, Exp 01/03/2023; 63067, Exp 01/01/2023; 63103, Exp 01/02/2023; 63120, Exp 01/03/2023; 63219, 63226, Exp 01/08/2023; 63263, Exp 01/09/2023; 63380, 63381, Exp 01/15/2023; 63433, Exp 01/16/2023; 63455, Exp 01/17/2023; 63537, Exp 01/22/2023; 63580, Exp 01/23/2023; 63721, Exp 01/29/2023; 63792, Exp 01/31/2023; 63888, Exp 02/05/2023; 63930, Exp 02/06/2023; 63959, Exp 02/07/2023; 64079, Exp 02/13/2023; 64109, Exp 02/14/2023; 64239, Exp 02/21/2023.