Enforcement Report - Week of April 19, 2023

Class II Drugs Event

Event ID:
91855

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/14/2023

Voluntary / Mandated:

Center Classification Date:
04/11/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero USA Inc
1035 Centennial Ave
Piscataway NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Pantoprazole Sodium Delayed Release Tablets USP 40mg, 1000-count bottles, Rx only, Manufactured for: Camber Pharmaceuticals Inc., Piscataway, NJ, 08854, By: Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahabubnagar- 509 301, India NDC 31722-713-10

Product Quantity:
2,352 bottles

Reason for Recall:
CGMP Deviations: Discoloration

Recall Number:
D-0530-2023

Code Information:
Lot #: PAN22542, Exp. Date: 9/2024

Class III Drugs Event

Event ID:
91872

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2023

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:
MEKTOVI (binimetinib) tablets, 15 mg, 180-count bottle, Rx only, Distributed by: Array BioPharma Inc., a wholly owned subsidiary of Pfizer Inc., Boulder, CO 80301. NDC: 70255-010-02

Product Quantity:
1,926 Bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: The carton and bottle labels state an expiry date of March 2026; the correct expiration date is February 2025.

Recall Number:
D-0532-2023

Code Information:
Lot W054586A, EXP 03/2026

Class III Drugs Event

Event ID:
91911

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Focus Health Group Inc
5802 Kingston Pike
Knoxville TN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Epinephrine Professional EMS, Epinephrine Convenience Kit, Epinephrine 1 mg/mL, Rx Only, Focus Health Group, Manufactured for: Focus Health Group, 5802 Kingston Pike, Knoxville, TN 37919. Incorrect NDC (kit): 24357-011-13

Product Quantity:
246 kits

Reason for Recall:
Labeling; Incorrect NDC number on outer carton of product.

Recall Number:
D-0535-2023

Code Information:
Lot numbers: 57943EMS, exp 5/31/2023; 56276EMS, exp 4/30/2024

Class III Drugs Event

Event ID:
91972

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/13/2023

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Bevacizumab 2.5 mg/0.1 mL, Solution for Injection in 1mL, silicone free slip tip syringe, each Syringe supplied in individually labeled poly envelopes (primary packaging). Repackaged by Pine Pharmaceuticals, Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150, Office Use Only, Not for Resale. Secondary packaging consists of a coated cardboard box, with order-specific label indicating lot number housed within order/container. NDC # 69194-0458-1

Product Quantity:
932 syringes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Lot code on primary packaging is incorrect.

Recall Number:
D-0531-2023

Code Information:
Lot # 66377, Exp. Date: 06/28/2023. Syringe may be labeled incorrectly as lot# 66316

Class III Drugs Event

Event ID:
91983

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2023

Voluntary / Mandated:

Center Classification Date:
04/10/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Norepinephrine Bitartrate Injection, USP, 4 mg/4 mL* (1 mg/mL), 4 mL Single-dose Fliptop Vial (NDC 47335-615-40); packaged in 10 x 4 mL Single-dose Fliptop Vials per carton (NDC 47335-615-44); Rx only, Manufactured by: Gland Pharma Limited, Hyderabad-502307 India; Distributed by: Sun Phamaceutical Industries, Inc., Cranbury, NJ 08512.

Product Quantity:
16,450 vials

Reason for Recall:
Failed Impurities/Degradation Specifications: Above the specification limits yielded for related substance norepinephrine sulfonic acid impurity during routine product monitoring.

Recall Number:
D-0529-2023

Code Information:
Lot Number: G1510001, Exp 11/2023; G151002, Exp. 12/2023; and G151003, Exp 02/2024