Enforcement Report - Week of March 29, 2023

Class II Drugs Event

Event ID:
91879

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/09/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd
Ridgefield CT United States

Distribution Pattern:
Product was distributed nationwide within the United States and PR

Associated Products

Product Description:
JARDIANCE (Empagliflozin), 25 mg Tablets, packaged in a) 30-count (NDC0597-0153-30) and b) 90-count (NDC 0597-0153-90) bottles, Rx only, Marketed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA and Eli Lilly and Company Indianapolis, IN 46285 USA

Product Quantity:
69,375 bottles

Reason for Recall:
Labeling: Label Mix-up

Recall Number:
D-0468-2023

Code Information:
Lot #: a) and b) E61835, exp. date JUN 2025

Class II Drugs Event

Event ID:
91882

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system) CII, 10mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5552-3.

Product Quantity:

Reason for Recall:
Defective Delivery System: Out of specification for shear.

Recall Number:
D-0470-2023

Code Information:
Lot#: 91955, Exp. 7/2023; 93039, Exp. 10/2023

Product Description:
Daytrana (methylphenidate transdermal system) CII, 15 mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5553-3

Product Quantity:

Reason for Recall:
Defective Delivery System: Out of specification for shear.

Recall Number:
D-0471-2023

Code Information:
Lot#: 91956, Exp. 6/2023; 92475, Exp. 7/2023

Product Description:
Daytrana (methylphenidate transdermal system) CII, 20mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5554-3.

Product Quantity:

Reason for Recall:
Defective Delivery System: Out of specification for shear.

Recall Number:
D-0472-2023

Code Information:
Lot#: 91957, 92197, Exp. 7/2023; 92476, Exp. 9/2023; 92477, Exp. 10/2023

Product Description:
Daytrana (methylphenidate transdermal system) CII, 30 mg, 30-count carton, Rx only, Manufactured for Noven Therapeutics, LLC., Miami by Noven Pharmaceuticals, Inc., NDC 68968-5555-3

Product Quantity:

Reason for Recall:
Defective Delivery System: Out of specification for shear.

Recall Number:
D-0473-2023

Code Information:
Lot#: 91474, 91959, Exp. 3/2023; 91958, Exp. 6/2023; 92478, Exp. 7/2023; 92479 & 92198, Exp. 8/2023; 92199, 93040, Exp. 9/2023; 93041, Exp. 10/2023.

Class III Drugs Event

Event ID:
91871

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

03/09/2023

Center Classification Date:
03/22/2023

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

Distribution Pattern:
USA nationwide.

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Dofetilide Capsules, 500 mcg (0.5 mg), 60-count bottle, Rx only, Manufactured by: Sun Pharmaceutical Industries Limited, Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India, NDC 47335-0063-86

Product Quantity:
1,920 bottles

Reason for Recall:
Failed Content Uniformity Specifications

Recall Number:
D-0474-2023

Code Information:
Lot # DND1541A, Exp 08/2024

Not Yet Classified Drugs Event

Event ID:
91768

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Global Pharma Healthcare Private Limited
A - 9 Sidco Pharmaceutical Complex Thiruporur
Chennai India

Distribution Pattern:
Product was imported by one distributor who further distributed the product via internet sales Nationwide in the USA.

Associated Products

Product Description:
Delsam Pharma's Artificial Eye Ointment (Mineral Oil 15%, White Petrolatum 83%), 3.5 grams (1/8 oz.) tube, Distributed By: Delsam Pharma Lic, Bronx, Newyork 10469, NDC 72570 122 35, UPC 3 72570 12235 3.

Product Quantity:
50,000 tubes

Reason for Recall:
Non-Sterility: FDA analysis found unopened tubes to be contaminated with bacteria.

Recall Number:

Code Information:
Batch # H29, Exp. Date 11/2023