Enforcement Report - Week of January 27, 2021

Class II Drugs Event

Event ID:
87016

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/30/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Allergan, PLC.
5 Giralda Farms
Madison NJ United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Refresh Relieva PF Preservative-Free Lubricant Eye Drops 0.33 fl oz (10 mL) Sterile Distributed by: Allergan, an AbbVie company Madison, NJ 07940 UPC 3 00236 63410 0, NDC 0023-6634-10.

Product Quantity:
100,634 bottles

Reason for Recall:
Labeling: Missing instructions for use insert

Recall Number:
D-0233-2021

Code Information:
Lots: T0392 Exp. Jul. 2022, T0843 Exp. Aug. 2022

Class II Drugs Event

Event ID:
87076

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/19/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Complete Pharmacy and Medical Solutions, LLC.
5829 Nw 158th St
Miami Lakes FL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
HUMAN CHORIONIC GONADOTROPIN 11,000 IU per vial Aso contains Mannitol 9%, Sodium Phosphate 2% in water for injection. Lyophilized, Unpreserved. Complete Pharmacy & Medical Solutions 5829 NW 158th St, Miami Lakes, FL 33014 Tel: 305-397-2035

Product Quantity:
1182 vials

Reason for Recall:
CGMP deviations: Lack of potency testing.

Recall Number:
D-0234-2021

Code Information:
Lot #: 40568 Use By Date: 01/30/2021

Product Description:
HUMAN CHORIONIC GONADOTROPIN 6,000 IU per vial Aso contains Mannitol 9%, Sodium Phosphate 2% in water for injection. Lyophilized, Unpreserved. Complete Pharmacy & Medical Solutions 5829 NW 158th St, Miami Lakes, FL 33014 Tel: 305-397-2035

Product Quantity:
2418 vials

Reason for Recall:
CGMP deviations: Lack of potency testing.

Recall Number:
D-0235-2021

Code Information:
Lot# 40604 Use By date, 01/30/2021

Product Description:
HUMAN CHORIONIC GONADOTROPIN 5,000 IU per vial Aso contains Mannitol 9%, Sodium Phosphate 2% in water for injection. Lyophilized, Unpreserved. Complete Pharmacy & Medical Solutions 5829 NW 158th St, Miami Lakes, FL 33014 Tel: 305-397-2035

Product Quantity:
1144 vials

Reason for Recall:
CGMP deviations: Lack of potency testing.

Recall Number:
D-0236-2021

Code Information:
Lot #: 40570 Use By Date 01/30/2021

Product Description:
HUMAN CHORIONIC GONADOTROPIN 1,250 IU per vial Aso contains Mannitol 9%, Sodium Phosphate 2% in water for injection. Lyophilized, Unpreserved. Complete Pharmacy & Medical Solutions 5829 NW 158th St, Miami Lakes, FL 33014 Tel: 305-397-2035

Product Quantity:
2400 vials

Reason for Recall:
CGMP deviations: Lack of potency testing.

Recall Number:
D-0237-2021

Code Information:
Lot #: 40548, Use By Date, 01/30/2021.

Class II Drugs Event

Event ID:
87135

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
03/19/2020

Center Classification Date:
01/19/2021

Recalling Firm:
Edge Pharma, LLC
856 Hercules Dr
Colchester VT United States

Distribution Pattern:
Distributed Nationwide in the USA

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Ceftazidime Sterile Ophthalmic Solution for Injection Preservative Free 11.25mg / 0.5ml (22.5mg/ml) 0.5ml per syringe. KEEP FROZEN UNTIL USE AND PROTECT FROM LIGHT SINGLE USE SYRINGE FOR INTRAOCULAR INJECTION Edge Pharma, LLC is an FDA-registered 503B outsourcing facility. This is a compounded (re-packaged) drug. Not for Resale, Hospital/Office use only. Edge Pharma, LLC 856 Hercules Dr. Colchester, VT 05446 Customer Service (USA) 1-802-992-1178

Product Quantity:
48 syringes

Reason for Recall:
Lack of Assurance of Sterility; the media used to conduct post-compounding sterility testing for the Methotrexate product was expired.

Recall Number:
D-0238-2021

Code Information:
Lot # 02-2020-04@4

Class II Drugs Event

Event ID:
87154

Status:
Ongoing

Recall Initiation Date:
01/07/2021

Center Classification Date:
01/15/2021

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Nitrofurantoin Capsules USP (Monohydrate/Macrocrystals), 100 mg, 100 per carton (10 capsules x 10 blister cards), Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC Carton: 68084-446-01; NDC Blister Card: 68084- 446-11

Product Quantity:
1948 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0232-2021

Code Information:
Lot # 193757, Exp 1/31/2022