Enforcement Report - Week of March 24, 2021

Class I Drugs Event

Event ID:
87283

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/16/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
1919 N Victory Pl
Burbank CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Spironolactone Tablets, USP, 25 mg, packaged in: a) 30-count bottles (NDC 63629-1064-01), b) 60-count bottles (NDC 63629-1064-02), c) 90-count bottles (NDC 63629-1064-03), Rx only, Manufactured by: Frontida BioPharm, Inc., Philadelphia, PA 19124 USA, Repackaged by: Bryant Ranch Prepack, Inc., Burbank, CA 91504 USA

Product Quantity:
35 bottles

Reason for Recall:
Labeling: Label Mix-Up - Prepackaged bottles labeled spironolactone 25 mg may contain spironolactone 50 mg tablets.

Recall Number:
D-0303-2021

Code Information:
a) Lot #: 148969, Exp 7/31/2022, b) Lot #: 148791, Exp 7/31/2022, c) Lot #: 148991, Exp 7/31/2022

Class II Drugs Event

Product Description:
Spironolactone Tablets, USP, 50 mg, packaged in 30-count bottles, Rx only, Manufactured by: Frontida BioPharm, Inc., Philadelphia, PA 19124 USA, Repackaged by: Bryant Ranch Prepack, Inc., Burbank, CA 91504 USA, NDC 63629-1067-01

Product Quantity:
12 bottles

Reason for Recall:
Labeling: Label Mix-Up - Prepackaged bottles labeled spironolactone 50 mg may contain spironolactone 25 mg tablets.

Recall Number:
D-0304-2021

Code Information:
Lot #: 148992, Exp 5/31/2022

Class II Drugs Event

Event ID:
87458

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/12/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
GA

Associated Products

Product Description:
Nortriptyline HCL capsules, 10 mg, packaged in 30-count bottles, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA, NDC 6191985330

Product Quantity:
17 bottles

Reason for Recall:
cGMP deviations: The quantity of active ingredient used for the product lot was inadvertently taken from an ingredient lot from an alternate supplier before that specific lot was formally qualified for use by the manufacturing site.

Recall Number:
D-0300-2021

Code Information:
Lot#: 28DE2002 Exp 10/31/22

Class II Drugs Event

Event ID:
87462

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Gabapentin Oral Solution, 250 mg/5 mL, 5 mL per unit dose cup, four unit dose cups per tray, For Institutional Use Only, Rx only, Hi-Tech Pharmacal Co., Inc, Amityville, NY 11701, NDC Tray: 50383-311-07; NDC Unit Dose Cup 50383-311-07

Product Quantity:
8,183 unit dose cups

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification for unknown impurity observed during 6 month stability testing

Recall Number:
D-0301-2021

Code Information:
Lot 369409, Exp. Date 05/2021; Lot 372393, Exp. Date 01/2022; Lot 373112, Exp. Date 04/2022

Class II Drugs Event

Event ID:
87492

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2021

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

Recalling Firm:
Sagent Pharmaceuticals Inc
1901 N Roselle Rd Ste 450
Schaumburg IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Phenylephrine HCl Injection, USP, 10 mg per mL, 1 mL per Single-Dose Vial packaged in 25 x 1 mL Single-Dose Vials per carton, For Intravenous Use, Rx only, Mfd. for: SAGENT Pharmaceuticals, Schaumburg, IL 60195; Made in India, NDC: 25021-315-01.

Product Quantity:
3716 cartons

Reason for Recall:
Lack of Assurance of Sterility: customer complaints of loose crimped vial overseals which may result in a non-sterile product.

Recall Number:
D-0305-2021

Code Information:
Lots: PHT8IB2, PHT9IB2, exp 08/2022; PHT1JB2, exp 09/2022

Class II Drugs Event

Event ID:
87498

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin CT United States

Distribution Pattern:
Product was distributed nationwide

Associated Products

Product Description:
Omeprazole Delayed-Release Capsules, USP, 20 mg, 1000 count bottles, Rx Only, distributed by Breckenridge Pharmaceutical, Inc., Berlin, CT, Manufactured by Tow Pharmaceutical Europe, S.L., Martorelles (Barcelona), Spain NDC 51991-643-10

Product Quantity:
3,146 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out-of-Specification results obtained for unknown impurities during stability testing.

Recall Number:
D-0308-2021

Code Information:
Lot # 191659, exp. date 05/2021

Class III Drugs Event

Event ID:
87348

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Methacholine Challenge 5-Syringe Test Kits, Sterile Inhalation Solution, Preservative Free, 3 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Dolchester, VT 06448 NDC # 05446-1600-05

Product Quantity:
213 kits

Reason for Recall:
Temperature Abuse; labeled with the incorrect room temperature (15-25 ¿C) storage conditions rather than the correct refrigerated (2 - 8 ¿C) storage conditions

Recall Number:
D-0306-2021

Code Information:
Lot # 12-2020-16@10, BUD 3-30-21 Lot # 11-2020-18@11, BUD 3-02-21

Class III Drugs Event

Event ID:
87452

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/19/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Distributed Nationwide in the USA.

Associated Products

Product Description:
Romidepsin Injecton, 27.5 mg/5.5 mL (5 mg/mL) Rx Only, 5.5 ml vial, Teva Pharmaceuticals USA, Inc. NDC 0703-4004-01

Product Quantity:
1,416 vials

Reason for Recall:
Failed Impurity/Degradation Specifications: Out-of-specifications results observed for impurities during stability testing.

Recall Number:
D-0309-2021

Code Information:
Lot # 31328184C, exp. date 11/2021 Lot # 31327686C, exp. date 08/2021 Lot # 31327685C, exp. date 08/2021

Class III Drugs Event

Event ID:
87514

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
12/22/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
PA only

Associated Products

Product Description:
Epinephrine/Lidocaine HCl, Sterile Ophthalmic Solution for Injection, 0.8 mL per syringe, Single Use Syringe, 0.025%/0.75%, Rx only, Edge Pharma LLC 856 Hercules Dr. Colchester, VT 05446, NDC 05446-0863-01

Product Quantity:
60 syringes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0307-2021

Code Information:
Lot #: 10-2020-13@8, exp. date 12/03/2020