Enforcement Report - Week of October 23, 2019

Class II Drugs Event

Event ID:
83705

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/04/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to MS, OH, RI, TN and Puerto Rico to distributors and wholesalers who may have further distributed the product to the retail level.

Associated Products

Product Description:
Pantoprazole Sodium Delayed Release Tablets, USP, 40 mg, packaged in 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd, Roorkee - 247661, India, Marketed by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801, NDC 59746-284-90

Product Quantity:
63,216 bottles

Reason for Recall:
CGMP Deviation: Presence of dark brown discoloration on edges of tablets.

Recall Number:
D-0145-2020

Code Information:
Lot # PA218P008, PA218P009, Exp 04/2021

Class II Drugs Event

Event ID:
83710

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/28/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Atlas Pharmaceuticals, LLC
711 E Carefree Hwy Ste 107
Phoenix AZ United States

Distribution Pattern:
Healthcare facilities/clinics in AZ and CO

Associated Products

Product Description:
Ascorbic Acid Sterile Injection Solution, 500 mg/mL, 50 mL vial, Non-Corn Source, Rx only, Atlas Pharmaceuticals, LLC, 711 E Carefree Hwy, Suite 107, Phoenix, AZ 85085, NDC 71591-500-50.

Product Quantity:
1646 vials

Reason for Recall:
Labeling: Not Elsewhere Classified; product is labeled as "Non-Corn Source" however the product is from a corn source.

Recall Number:
D-0144-2020

Code Information:
Lot #: S-60162, BUD 10/12/2019; S-60176, BUD 11/2/2019; S-60187, BUD 11/11/2019; S-60189, BUD 11/16/2019; S-60190, BUD 11/16/2019; S-60222, BUD 01/20/2020

Class II Drugs Event

Event ID:
83796

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Spectrum Laboratory Products
14422 S San Pedro St
Gardena CA United States

Distribution Pattern:
Product was distributed to compounding pharmacies and labs in CA, CO, MD, SC.

Associated Products

Product Description:
Fentanyl Citrate USP, Active Pharmaceutical Ingredient, Spectrum Chemical MFG. CORP., Gardena, CA 90248 NDC 49452-0032-06

Product Quantity:
29.1 grams

Reason for Recall:
CGMP Deviations: Received notice from supplier that there is potential glass contamination.

Recall Number:
D-0141-2020

Code Information:
Lot # 1HE0899, 1IB0005, Exp 02/28/2023

Class II Drugs Event

Event ID:
83848

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/19/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Dextroamphetamine Sacharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, Mixed Salts of a single Entity Amphetamine Product), 20mg, 100-count bottle, RX Only, Distributed by: Aurobindo Pharma USA Inc., Dayton, NJ 08810, NDC 13107-073-01

Product Quantity:
11,129 100-count bottles

Reason for Recall:
Superpotent Drug: Amphetamine Mixed Salts 20mg have been found to be out of specification for weight and thickness.

Recall Number:
D-0143-2020

Code Information:
Batch 07319032A1, Exp 02/2021

Class II Drugs Event

Event ID:
83960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Product was shipped to 8 distributors who may have further distributed the product.

Associated Products

Product Description:
Pioglitazone Hydrochloride Tablets USP 15 mg, 30 count bottles, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ, Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, India NDC 33342-054-07

Product Quantity:
31,968 bottles

Reason for Recall:
Superpotent

Recall Number:
D-0140-2020

Code Information:
Lot # BPF901A, exp. date 12/2021

Class II Drugs Event

Event ID:
84011

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/09/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ingenus Pharmaceuticals Llc
4190 Millenia Blvd
Orlando FL United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Leucovorin Calcium Injection, USP 500 mg*/50 mL (10 mg/mL) 50 mL Single-Dose Vial NDC 50742-464-50 Rx Only Ingenus Pharmaceuticals, LLC. Orlando, FL 32839

Product Quantity:
16485 vials

Reason for Recall:
Crystallization: Presence of particulate matter identified as API crystallization

Recall Number:
D-0146-2020

Code Information:
Lot#: 18048, 18049 Exp. 04/2020; 18050 Exp 05/2020; 19036 Exp 12/2020

Class III Drugs Event

Event ID:
83851

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/04/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Methylphenidate Hydrochloride Oral Solution 5mg per 5mL, 500 mL Bottle, Sugar Free Alcohol Free, Rx Only, Mfd by: KVK Tech, Inc., Newtown, PA 18940, NDC 10702-0163-50.

Product Quantity:
384 bottles

Reason for Recall:
Presence of Foreign Substance; Fiber particles.

Recall Number:
D-0142-2020

Code Information:
Batch # 15315A, Exp. 02/2021