Enforcement Report - Week of September 22, 2021

Class I Drugs Event

Event ID:
86266

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/13/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Grupo Asimex de Mexico SA de CV
Mario Pani No 750 Piso 10-C Col. Santa Fe Cuajimalpa, Cuajimalpa De Morelos
Ciudad De Mexico Mexico

Distribution Pattern:
Distributor in FL who further distributed Nationwide in the USA

Associated Products

Product Description:
Florance Morris ANTISEPTIC Hand Sanitizer (ethyl alcohol 70%), packaged in a) 8.45 fl oz (250 mL) bottles and b) 33.81 fl oz (1L) bottles, Distributed by: Asimex International LLC, 9100 S Dadeland Blvd, Ste 912, Miami, FL 33156, COUNTRY OF ORIGIN: MEXICO.

Product Quantity:
22,680 bottles

Reason for Recall:
Chemical Contamination: FDA analysis found the product contains methanol, additionally it is sub-potent for ethanol content.

Recall Number:
D-0795-2021

Code Information:
All lots including but not limited to: 200520673 and 200601685

Class I Drugs Event

Event ID:
88454

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Nationwide within the United States and Canada

Associated Products

Product Description:
Lidocaine Hydrochloride Topical Solution, USP, 4% , 50 mL glass bottles, Rx Only, Teligent Pharma Inc. Buena, New Jersey 08310, NDC 52565-009-50.

Product Quantity:
32,544 glass bottles

Reason for Recall:
Superpotent Drug

Recall Number:
D-0800-2021

Code Information:
Lot #:14218, Exp. Date 08/2022

Class I Drugs Event

Event ID:
88467

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/14/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Ebay Seller - John Nguyen
15710 Bryan Creek Ct
Houston TX United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Hydro Pinapple Burn Max Health Thach Dua, packaged in a box containing 20g x 10 goi/sachets, MATXI CORP, UPC 8 936188 880108

Product Quantity:
35 boxes

Reason for Recall:
Marketed without an approved NDA/ ANDA - presence of undeclared sibutramine

Recall Number:
D-0797-2021

Code Information:
All lots within expiry.

Class I Drugs Event

Event ID:
88620

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
ICU Medical Inc
600 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
AMINOSYN II 15% An Amino Acid Injection, Sulfite-Free, 2000 mL in flexible containers, Rx ONLY, Hospira, Inc., Lake Forest, IL 60045. NDC 0409-7171-17

Product Quantity:
2,112 Flexible Containers

Reason for Recall:
Presence of Particulate Matter: Particulate matter identified as fibers, hair, and proteinaceous material along with other particles, found in retain smples.

Recall Number:

Code Information:
Lot: 4989094 Exp. 01-APR-2022

Class II Drugs Event

Event ID:
86266

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/13/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Grupo Asimex de Mexico SA de CV
Mario Pani No 750 Piso 10-C Col. Santa Fe Cuajimalpa, Cuajimalpa De Morelos
Ciudad De Mexico Mexico

Distribution Pattern:
Distributor in FL who further distributed Nationwide in the USA

Associated Products

Product Description:
Florance Morris ANTISEPTIC Hand Sanitizer (ethyl alcohol 70%), packaged in a) 8.45 fl oz (250 mL) bottles and b) 33.81 fl oz (1L) bottles, Distributed by: Asimex International LLC, 9100 S Dadeland Blvd, Ste 912, Miami, FL 33156, COUNTRY OF ORIGIN: MEXICO.

Product Quantity:

Reason for Recall:
CGMP Deviations: All other lots are being recalled because they were manufactured under the same conditions as the product lots found to contain methanol.

Recall Number:
D-0796-2021

Code Information:
All lots including but not limited to a) 200520674 and b) 200525677

Class II Drugs Event

Event ID:
88488

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/16/2021

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:
USA Nationwide

Associated Products

Product Description:
Betamethasone Dipropionate Lotion USP (Augmented), 0.05%, packaged in a) 30 mL bottle (NDC 61748-480-30), b) 60 mL bottle (NDC 61748-480-60), Rx only, Manufactured by: Hi-Tech Pharmacal Co. Inc., Amityville,NY 11701

Product Quantity:
264 bottles; 48 bottles lot 372286 and 216 bottles lot 372289

Reason for Recall:
Failed impurities/degradation specification: Out of Specification for an unknown impurity observed in topical product.

Recall Number:
D-0802-2021

Code Information:
Lot #: a) 372286, 372289, Exp 1/31/2022, b) 372286, 372289, Exp 1/31/2022

Class II Drugs Event

Event ID:
88506

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/13/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rhodes Pharmaceuticals, L.P.
498 Washington St
Coventry RI United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Oxycodone Hydrochloride Tablets, USP, 10 mg, 100 count bottle, Rx only, Marketed by: Rhodes Pharmaceuticals L.P., Coventry RI 02816, Manufactured by: Purdue Pharma L.P., Stanford, CT 06901 NDC 42858-002-01

Product Quantity:
55,344/100 count bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules; A single foreign tablet Hydrochlorothiazide/Lisinopril 25/20 was found in one bottle

Recall Number:
D-0794-2021

Code Information:
Lot # WP5K0Y, exp. date 02/28/2023

Class II Drugs Event

Event ID:
88515

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/18/2021

Center Classification Date:
09/16/2021

Recalling Firm:
Prescription Labs Inc dba Greenpark
4061f Bellaire Blvd
Houston TX United States

Distribution Pattern:
Nationwide within the United States

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Spironolactone Ophthalmic Solution 0.005 mg/mL, 15 mL bottles, Rx only, Greenpark Compounding Pharmacy

Product Quantity:
350 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0804-2021

Code Information:
Lots: 03012021@35; 04132021@10; 05102021@12; 06012021@28; 07012021@25; 03012021@36; 04132021@12; 05102021@11; 06012021@29; 07132021@14; 03152021@9; 06162021@21; 07132021@16; 03152021@10; 06162021@22

Class II Drugs Event

Event ID:
88653

Status:
Ongoing

Recall Initiation Date:
09/09/2021

Center Classification Date:
09/15/2021

Recalling Firm:
Vi-Jon, Inc.
1 Swan Dr
Smyrna TN United States

Distribution Pattern:
Distributed Nationwide in the USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Kroger 70% Isopropyl Alcohol First Aid Antiseptic 32 FL OZ (1 QT) 946 mL 5 Dist. By The Kroger Co., Cincinnati, Ohio 45202 NDC 30142-810-45, UPC 0 11110 37049

Product Quantity:
21,156 bottles

Reason for Recall:
Labeling: Label Mix-Up.The recall has been initiated after receiving one complaint about incorrect labeling.The primary label on the front and back label on some of the bottles have 70% Isopropyl Alcohol affixed to the containers. However, the product inside the bottle is Hydrogen Peroxide, Topical Solution USP with active ingredient Hydrogen Peroxide (stabilized) 3%, 32 FL Ounces

Recall Number:
D-0799-2021

Code Information:
Lot: 0542077 Exp. 07/2023

Class II Drugs Event

Event ID:
88662

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/16/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Promise Pharmacy, LLC
31818 Us Highway 19 N
Palm Harbor FL United States

Distribution Pattern:
AZ, CO, FL, IL, NJ

Associated Products

Product Description:
MIC+Methyl B12 injection Methionine Inositol Choline+Methylcobalamin 25 mg/50 mg/50 mg/1 mg/mL, 10 mL vial sterile, Rx only, Promise Pharmacy 31818 US Hwy 19N Palm Harbor FL 34684 1-888-3PROMIS

Product Quantity:
57 vials

Reason for Recall:
Lack of processing controls

Recall Number:
D-0803-2021

Code Information:
Lot# 06152021@2, Exp 09/13/2021

Class III Drugs Event

Event ID:
88609

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/14/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Candesartan Cilexetil Tablets, USP 16 mg, 30 count bottles, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 NDC 0378-3231-93

Product Quantity:
21,094

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification for Related Compound

Recall Number:
D-0798-2021

Code Information:
Lot # 3107334, exp. date October 2021

Class III Drugs Event

Event ID:
88619

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Meitheal Pharmaceuticals Inc
8700 W Bryn Mawr Ave Ste 600
Chicago IL United States

Distribution Pattern:
Nationwide within the USA and India

Associated Products

Product Description:
Glycopyrrolate Injection, USP 4mg per 20mL, 20 mL Multi-Dose Vials, Rx only, Mfd for Meitheal Pharmaceuticals, Chicago, IL 60631. NDC 71288-408-21

Product Quantity:
1,160 ten-pack cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0801-2021

Code Information:
Lot #: G0010120, Exp. Date December 2021; G0080520, Exp. Date April 2022; G0090221, G0100221, Exp. Date January 2023