Enforcement Report - Week of October 13, 2021

Class I Drugs Event

Event ID:
88335

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/16/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/04/2021

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Alpha-Tek LLC
3280 E Hemisphere Loop Suite 190
Tucson AZ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
ALPHA MALE+ Male Enhancer, fruit chew strips, 1 strip per foil pouch, Distributed by Umbrella Labs, Made in the USA, UPC 8 60003 03770 6. Also manufactured for and distributed by: Alpha Male Plus, Tucson, AZ UPC 8 60003 74518 2 (pouch), UPC 8 60003 74512 0(carton)

Product Quantity:
Unknown

Reason for Recall:
Marketed Without an Approved NDA/ANDA: FDA analysis determined the presence of tadalafil

Recall Number:
D-0001-2022

Code Information:
All lots within expiry

Class I Drugs Event

Event ID:
88547

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Azurity Pharmaceuticals, Inc.
841 Woburn St
Wilmington MA United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Firvanq (vancomycin hydrochloride for oral solution), Vancomycin 50 mg/mL Kit, Each Kit Includes: 1 bottle containing 7.7 g Vancomycin Hydrochloride USP, powder for oral solution and 1 bottle containing 145 mL Grape Flavored Diluent for reconstitution per carton, Rx only, Manufactured for: Azurity pharmaceuticals, Wilmington, MA 01887, NDC 65628-206-05.

Product Quantity:
2,751 kits

Reason for Recall:
Product Mix-up: Incorrect diluent component included in the kit.

Recall Number:
D-0003-2022

Code Information:
Lot # 21035, Exp 7/31/2022

Class II Drugs Event

Event ID:
88593

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/07/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RISING PHARMACEUTICALS
2 Tower Center Blvd
East Brunswick NJ United States

Distribution Pattern:
to be entered

Associated Products

Product Description:
Meclizine HCl Tablets, 25 mg, packaged in 100-count HDPE bottle, Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816, Manufactured by: Aurex laboratories LLC, East Windsor, NJ 08520, NDC 16571-752-01

Product Quantity:
1,344 bottles

Reason for Recall:
Labeling: Incorrect Instructions

Recall Number:
D-0005-2022

Code Information:
Lot # CB21024, Exp 2/2023

Class II Drugs Event

Event ID:
88772

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AMIVAS (US), LLC
100 Tuscanney Dr Suiteb2
Frederick MD United States

Distribution Pattern:
Product was distributed to 3 major distributors who may have further distributed the product to various medical centers, hospitals and hospital

pharmacies nationwide in the USA.

Associated Products

Product Description:
Artesunate for Injection, 110 mg/vial, packaged in a) 2x2 pack containing 2 Single-dose vials artesunate (73607-001-01) and 2 vials sterile diluent (NDC 73607-001-02) per carton (NDC 73607-001-11); 4x4 pack containing 4 Single-dose vials artesunate (73607-001-01) and 4 vials sterile diluent (NDC 73607-001-02) per carton (NDC 73607-001-10), Rx only, Mfg for: Amivas, LLC, 1209 Orange St., Wilmington, Delaware 19801.

Product Quantity:
292 cartons

Reason for Recall:
Lack of Assurance of Sterility: Air filter failed post integrity test leading to a lack of sterility assurance.

Recall Number:
D-0002-2022

Code Information:
Manufacturer Lot Numbers: AR479E01, exp. date 11/03/2022; AR479E02, exp. date 11/09/2022; AR479E03, exp. date 11/16/2022; Cardinal Health Packaging Solutions Lot Numbers: 7507001 and 7508001

Class II Drugs Event

Event ID:
88823

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/04/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/07/2021

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:
Distributed Nationwide in the USA

Associated Products

Product Description:
Betaxolol Ophthalmic Solution, USP, 0.5%, (Betaxolol HCl 5.6 mg/mL), 5 mL dropper bottle, Rx only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Carton NDC: 17478-705-10, Bottle NDC 17478-705-11

Product Quantity:
10,210 bottles

Reason for Recall:
Microbial Contamination of Sterile Products: Confirmed sterility failure identified during stability testing at the 12-month time point.

Recall Number:
D-0004-2022

Code Information:
Lot 0B61A, Exp 01/31/2022