Enforcement Report - Week of August 24, 2022

Class I Drugs Event

Event ID:
86414

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/15/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
MEDEK LLC
315 E Business Highway 83
Alamo TX United States

Distribution Pattern:
Texas

Associated Products

Product Description:
M Hand Sanitizer Ethyl Alcohol Antiseptic 80%v/v, Topical Solution 128 oz/3,785 mL, Made in Mexico by: Grupo Plast-Y-Kosas S.A. de C.V. Puebla 105 Col. Rodriguez Reynosa, Tam, Mexico C.P. 88630, NDC Code: 77797-001-01, Distributed by: Medek, LLC 315 E. Business Hwy 83 Alamo, TX 78516, NDC Code: 75432-001-02.

Product Quantity:
256 bottles

Reason for Recall:
Chemical Contamination and Subpotent Drug: FDA analysis found product to contain methanol and below label claim for ethanol.

Recall Number:
D-1342-2022

Code Information:
All lots

Class II Drugs Event

Event ID:
90616

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Rifampin Capsules, USP, 150 mg, 30 count HDPE bottles, Rx Only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, 21202 NDC: 68180-658-06

Product Quantity:
7,872/30 count bottles

Reason for Recall:
CGMP Deviations:OOS result was observed in 1-Methyl-4-Nitroso Piperazine (MNP) impurity.

Recall Number:
D-1343-2022

Code Information:
Lot #A200170, exp. date December 2023

Class II Drugs Event

Event ID:
90618

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Fulvestrant Injection 250mg/5mL (50 mg/mL), Contains 2 Single-Dose Prefilled Syringes, Rx Only, Product of India, Manufactured by: Cadila Healthcare Limited, Ahmadabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc.m Pennington, NJ 08534, NDC 70710-1688-8.

Product Quantity:
1116 boxes

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1351-2022

Code Information:
Lot # B200076; Exp 31 JAN 2024

Class II Drugs Event

Event ID:
90644

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aire-Master of America Inc
1821 N State Highway Cc
Nixa MO United States

Distribution Pattern:
Florida, Illinois, Iowa, New Jersey

Associated Products

Product Description:
Avant Foaming Hand Sanitizer, ethanol 62%, a) 18 fl. oz. bottle (530 mL), b) 1000 mL (33.9 fl. oz.) pouch, c) 55 gallon drum, Fragrance Free, Manufactured for B4 Brands, Lisbon, Iowa 62253

Product Quantity:
18 oz bottle: 11,435 bottles; 1000 mL pouch: 4,116 pouches, c) 2 drums

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1355-2022

Code Information:
[Product number], lot code, expiry: a) [46016] Lot 722770, exp 07/22 b) [46017] Lot 722995-exp 07/22, 727370-exp 07/23, 727898-exp 09/23, 728005-exp 08/23, 729522-exp12/23, 730412-exp 03/24, 730861-exp 04/24 c) [46138] Lot 725188-exp 12/22

Product Description:
Avant Foaming Hand Sanitizer Ophardt, Fragrance Free, 1000 mL (33.9 fl. oz.) per plastic carton, Manufactured for B4 Brands, Lisbon, Iowa 52253

Product Quantity:
9,176 cartons

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1356-2022

Code Information:
Product Number 46076 Lot 722896-exp 07/22, 722996-exp 07/22

Product Description:
Stage 2-Ophardt Foaming Hand Sanitizer, Fragrance-Free, 1000 mL (33.9 fl. oz.) per bottle, Manufactured for 2XL Corporation, 2 Gateway Ct, Ste A, Bolingbrook, IL 60440

Product Quantity:
4,632 cartons

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1357-2022

Code Information:
Product Number 46101, Lots 722712-exp 07/22, 724755-exp 11/22, 725054-exp 12/22

Product Description:
Protect U Guard Foaming Hand Sanitizer Ophardt, Fragrance Free, 1000 mL (33.9 fl. oz.) per carton, Manufactured for Protect U Guard, Tampa 33606.

Product Quantity:
960 cartons

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1358-2022

Code Information:
Product Number 46112, Lots 722782 -exp 08/22

Product Description:
Protect U Guard Foaming Hand Sanitizer, Fragrance Free, 18 fl/oz. (530 mL) per bottle, Manufactured for Protect U Guard, Tampa, FL 33606

Product Quantity:
5,064 bottles

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1359-2022

Code Information:
Product Number 46111, Lot 722781-exp 09/22

Product Description:
Common Sense Fragrance Free Hand Sanitizer, 250 Gallon Tote, Microbe Solutions, LLC, 344-5 Route 9, Suite 237, Lanoka Harbor, NJ 08734

Product Quantity:
4 totes

Reason for Recall:
CGMP Deviations: product manufactured using deionized water from a system lacking appropriate microbial control post deionization.

Recall Number:
D-1360-2022

Code Information:
Product Number 46137, Lot 724640-exp 11/22, 729955-exp 01/24

Class II Drugs Event

Event ID:
90676

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc
5605 Centerpoint Ct Ste B
Gurnee IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
PrednisoLONE Oral Solution USP, 15 mg per 5 mL, 240 ml bottle, Rx Only, HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. NDC: 50383-042-24

Product Quantity:
14,712 bottles

Reason for Recall:
Defective Container: Product has incomplete induction seals.

Recall Number:
D-1361-2022

Code Information:
Lot# 379804, Exp. 8/31/2023

Class II Drugs Event

Event ID:
90699

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Acetaminophen Injection, 10 mg/mL, 1,000 mg/100 mL, 100 mL VIAFLO container bag, Single Dose Container, For Intravenous Use Only, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA; NDC 36000-306-60

Product Quantity:
85,680 bags

Reason for Recall:
Temperature Abuse: Product distributed in refrigerated trucks with labels attached to pallets indicating "Refrigerate Upon Arrival", however product is labeled to be stored in a controlled room temperature environment.

Recall Number:
D-1348-2022

Code Information:
Lots: 20K19G64T1, Exp 10/31/2022; 21K23G65, 21K25G65, 21K26G65, 21K29G67, Exp 10/31/2023; 21L10G65, 21L13G66, 21L14G66, 21L15G65, Exp 11/30/2023

Class II Drugs Event

Event ID:
90703

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Sc Inc
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Ketorolac Tromethamine Injection, USP 60 mg/2 mL (30 mg/mL), packaged in 2 mL single dose vials, Rx Only, Nephron Pharmaceutical Corporation 4500 12th Street Extension West Columbia, SV 29172, NDC 0487-6232-01

Product Quantity:
5040 vials

Reason for Recall:
cGMP Deviations: deviations leading to potential cross-contamination.

Recall Number:
D-1354-2022

Code Information:
Lot#: 023011 Exp 8/31/2022

Class II Drugs Event

Event ID:
90718

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/16/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Sterile Compounding Center LLC
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
PF-Neostigmine Methylsulfate Injection, USP, 3 mg/3 mL (1 mg/mL), One 3 mL Unit-Dose Vial, packaged in 30 x 3 mL Sterile Unit-Dose Vials per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th Street Extension, West Columbia, SC 29172; NDC 69374-932-33

Product Quantity:
13,500 vials

Reason for Recall:
CGMP Deviations: Potential for cross-contamination due to product carryover during manufacturing.

Recall Number:
D-1344-2022

Code Information:
Lot: NE1057A, Exp. 10/23/2022

Product Description:
Trisodium Citrate 0.5% Solution, (0.5%/4L), contains Per Liter: Sodium 140 mmol/L, Chloride 86 mmol/L, Citrate 18 mmol/L, 4000 mL IV bag, packaged in 1 x 1 IV bag per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th Street Extension, West Columbia, SC 29172; NDC 69374-910-04

Product Quantity:
294 bags

Reason for Recall:
CGMP Deviations: Potential for cross-contamination due to product carryover during manufacturing.

Recall Number:
D-1345-2022

Code Information:
Lots: TC2007D, Exp. 8/26/2022; TC2010A, Exp. 9/25/2022

Product Description:
PF-0.125% Bupivacaine HCl Injection, USP, 625 mg/500 mL (1.25 mg/mL), 500 mL bag, packaged in 10 x 1 IV Bag per case, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th Street Extension, West Columbia, SC 29172; NDC 69374-970-05

Product Quantity:
2030 bags

Reason for Recall:
CGMP Deviations: Potential for cross-contamination due to product carryover during manufacturing.

Recall Number:
D-1346-2022

Code Information:
Lots: BH2003A, Exp. 8/19/2022; BH2011A, Exp. 11/9/2022

Product Description:
PF-Labetalol HCl Injection, USP, 20 mg/4 mL (5 mg/mL), One 4 mL Unit-Dose Vial, packaged in 30 x 4 mL Sterile Unit-dose Vials per carton, Rx Only, Nephron 503B Outsourcing Facility, 4500 12th Street Extension, West Columbia, SC 29172; NDC 69374-946-34

Product Quantity:
33,870 vials

Reason for Recall:
CGMP Deviations: Potential for cross-contamination due to product carryover during manufacturing.

Recall Number:
D-1347-2022

Code Information:
Lot: LB2005A, Exp 3/2/2023

Class III Drugs Event

Event ID:
90677

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/27/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Azacitidine for Injection, 100 mg Lyophilized Powder, Single-Dose Vials, Rx Only, Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213 India. Manufactured for BluePoint Laboratories. NDC 68001-0313-56

Product Quantity:
4,160 vials

Reason for Recall:
Subpotent Drug

Recall Number:
D-1349-2022

Code Information:
Lot #: FE22001A, Exp. Date 01/2024

Class III Drugs Event

Event ID:
90682

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akron Pharma, Inc.
373 Us Highway 46 Ste 117
Fairfield NJ United States

Distribution Pattern:
Product was distributed to 6 distributors/wholesalers who may have further distributed the product.

Associated Products

Product Description:
Acetaminophen 325 mg tablets, packaged in a) 100-count bottle (NDC 71399-8024-01); b) 1000-count bottle (NDC 71399-8024-02), Akorn Pharma Manufactured for: Akorn Pharma, Inc., Fairfield, NJ

Product Quantity:
301,382 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Imprint "AP 325" is missing from the tablet.

Recall Number:
D-1352-2022

Code Information:
Lot #: AXA2001, AXA2002, AXA2003, AXA2004, AXA2005, AXA2006, AXA2007, AXA2008, AXA2009, AXA2010, AXA2011, AXA2012, AXA2013, AXA2014, Exp Feb-23; AKK2021, AKK30421, AKK40421, AKK50421, AKK60421, AKK70421, AKK80421, AKK90421, Exp Mar-24; AKL10421, AKL20421, AKL10521, AKL20521, AKL30521, AKL40521, AKL50521, AKL60521, AKL70521, AKL80521, AKL90521, Exp Apr-24; AKM10521, Exp Apr-24; AKA10621, AKA20621, AKA30621, AKA40621, AKA50621, AKA60621, AKA70621, AKA80621, AKA90621, Exp May-24; AKB10621, Exp May-24

Product Description:
Acetaminophen 500 mg tablet, Extra Strength, packaged in a) 100-count bottle (NDC 71399-8022-01), b) 1000-count bottle (NDC 71399-8022-02), Akorn Pharma Manufactured for: Akorn Pharma, Inc., Fairfield, NJ

Product Quantity:
30,325 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Imprint "AP 325" is missing from the tablet.

Recall Number:
D-1353-2022

Code Information:
Lot#: AXA2014, Exp Feb-23; AXB2001, Exp Nov-22; AXB2002, AXB2003, AXB2004, AXB2005, AXB2006, AXB2007, AXB2008, AXB2009, AXB2010, AXB2011, Exp Dec-22; AXB2012, AXB2013, AXB2014, AXB2015, AXB2016, AXB2017, AXB2018, AXB2019, AXB2020, AXB2021, AXB2022, AXB2023, AXB2024, AXB2025, AXB2026, AXB2027, Exp Feb-23

Class III Drugs Event

Event ID:
90712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
HERON THERAPEUTICS, INC.
4242 Campus Point Ct Ste 200
San Diego CA United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Zynrelef (bupivacaine and meloxicam), 400 mg bupivacaine and 12 mg meloxicam single dose application, packaged in a kit, Rx only, Manufactured for Heron Therapeutics, Inc., San Diego, CA, NDC 47426-301-02

Product Quantity:
1790 kits

Reason for Recall:
Defective Delivery System: An incorrect 10 mL (12 mL) Luer (slip) syringe packaged in one lot of Zynrelef 400 mg/12 mg kit

Recall Number:
D-1335-2022

Code Information:
Lot #: 01126739, Exp 7/31/2023