Enforcement Report - Week of April 13, 2022

Class I Drugs Event

Event ID:
89778

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/08/2022

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

Recalling Firm:
Adamis Pharmaceuticals Corporation
11682 El Camino Real Ste 300
San Diego CA United States

Distribution Pattern:
Nationwide in the U.S.A.

Associated Products

Product Description:
SYMJEPI (epinephrine injection, USP) 0.3 mg, (0.3 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton, Rx Only, Manufactured for Adamis Pharmaceuticals Corp.; San Diego, CA 92130; Distributed by USWM, LLC., Louisville, KY 40241, Made in Belgium, NDC 78670-130-02

Product Quantity:
25,103 cartons

Reason for Recall:
Defective Delivery System: Potential clogging of the needle preventing the dispensing of epinephrine.

Recall Number:
D-0763-2022

Code Information:
Lot #: 21041W, Exp. 8/31/2022; 21081W, Exp. 11/30/2022; 21102W, Exp. 2/28/2023

Product Description:
SYMJEPI (epinephrine injection, USP) 0.15 mg (0.15 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton, Rx Only, Manufactured for Adamis Pharmaceuticals Corp.; San Diego, CA 92130; Distributed by USWM, LLC., Louisville, KY 40241, Made in Belgium, NDC 78670-131-02.

Product Quantity:
2,500 cartons

Reason for Recall:
Defective Delivery System: Potential clogging of the needle preventing the dispensing of epinephrine.

Recall Number:
D-0764-2022

Code Information:
Lot # 21101Y, Exp. 11/30/2022

Class II Drugs Event

Event ID:
88937

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Sandoz, Inc
506 Carnegie Ctr Ste 400
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Orphenadrine Citrate Extended-Release Tablets, USP 100 mg, Rx Only, 100 Tablets, Manufactured by Sandoz Inc., Princeton, NJ 08540 NDC 0185-0022-01.

Product Quantity:
7908 bottles(790,800 extended release tablets)

Reason for Recall:
CGMP Deviations:Nitrosamine impurity (NMOA) above the acceptable daily limit.

Recall Number:
D-0753-2022

Code Information:
Lot #: JX6411, JX6413, Exp. 05/2022 Lot #: KC0723,KC3303, Exp. 08/2022 Lot #: KE4348, KE7169,KE4349, Exp. 11/2022 Lot #: KL3199, KM0072,KS3939, Exp. 03/2023 Lot #: LA7704, LA7703,LA9243, Exp. 11/2023

Class II Drugs Event

Event ID:
89803

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2022

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

Recalling Firm:
Vitae Enim Vitae Scientific, Inc.
3030 Bunker Hill St Ste 203
San Diego CA United States

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
TETRACAINE 1% Tetracaine HCl Injection, USP, 20mg/2mL (10mg/mL), 10 x 2ml Single Use Vials per box, Rx only, Manufactured for Cameron Pharmaceuticals, LLC., NDC 42494-437-10.

Product Quantity:
722 boxes

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0741-2022

Code Information:
Lot #: 21VTHI017, 21VTHI018, 21VTHI019, Exp 5/31/2023

Product Description:
PAPAVERINE HYDROCHLORIDE Injection, USP, 60 mg/2mL (30 mg/mL), packaged as a) 25 x 2mL Single Use Vials per box (NDC 72516-024-25) and b) 10 x 2mL Single Use Vials per box (NDC 72516-024-10); Manufactured for Oryza Pharmaceuticals, Inc.

Product Quantity:
a) 2,098 boxes; b) 700 boxes

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0742-2022

Code Information:
Lot #: a) 20VPHI037, 20VPHI038, 20VPHI039, Exp 12/31/2022; 21VPHI021, 21VPHI022, 21VPHI023, Exp 6/30/2023; 21VPHI047, 21VPHI048, Exp 10/31/2023; b) 21VPHI023, Exp 6/30/2023

Product Description:
PHENOBARBITAL Sodium Injection, USP, 65mg/mL, packaged as a) 25 x 1 mL Vials per box (NDC 42494-415-25) and b) 3 x 1 mL Vials per box (NDC 42494-415-03), Rx only, Manufactured for Cameron Pharmaceuticals, LLC.

Product Quantity:
a) 21,501 boxes; b) 4,846 boxes

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0743-2022

Code Information:
Lot #: a) 20VPSI007, Exp 3/31/2022; 20VPSI015, Exp 5/30/2022; 20VPSI018, Exp 6/1/2022; 20VPSI032, Exp 11/30/2022; 21VPSI002, 21VPSI003, Exp 1/31/2023; 21VPSI006, Exp 3/31/2023; 21VPSI012, 21VPSI020, Exp 5/31/2023; 21VPSI035, Exp 7/31/2023; 21VPSI037, 21VPSI038, Exp 8/31/2023; 21VPSI043, 21VPSI044, Exp 10/31/2023; 21VPSI050, 21VPSI051, Exp 11/30/2023; 22VPSI004, Exp 7/31/2024; 22VPSI006, Exp 8/31/2024; b) 20VPSI008, Exp 3/31/2022; 20VPSI019, Exp 6/30/2022; 21VPSI050, Exp 11/30/2023,

Product Description:
PHENOBARBITAL Sodium Injection, USP, 130 mg/mL, packaged as a) 25 x 1 mL Vials per box (NDC 42494-416-25) and b) 3 x 1mL Vials per box (NDC 42494-416-03), Rx only, Manufactured for Cameron Pharmaceuticals, LLC.

Product Quantity:
a) 18,531 boxes; b) 4,492 boxes

Reason for Recall:
Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.

Recall Number:
D-0744-2022

Code Information:
Lot # a) 20VPSI011, Exp. 4/30/2022; 20VPSI014, Exp. 5/31/2022; 20VPSI020, 20VPSI022, 20VPSI023, Exp. 7/31/2022; 21VPSI007, Exp. 3/31/2023; 21VPSI013, Exp. 5/31/2023; 21VPSI027, Exp. 6/30/2023; 21VPSI039, Exp. 8/31/2023; 21VPSI042, Exp. 10/31/2023; 21VPSI049, Exp. 11/30/2023; 21VPSI052, Exp. 12/31/2023; 22VPSI005, Exp. 7/31/2024; 22VPSI007, Exp. 8/31/2024; Lots: b) 22VPSI007, Exp. 8/31/2024; 20VPSI009, Exp. 3/31/2022; 20VPSI020, Exp. 7/31/2022; 21VPSI039, Exp. 8/31/2023; 22VPSI005, Exp. 7/31/2024.

Class II Drugs Event

Event ID:
89814

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
DASH Pharmaceuticals LLC
2 Park Way
Upper Saddle River NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Sucralfate Oral Suspension, USP 1g/10mL, packaged in a) 40 case of 10 mL unit Dose Cups (NDC 69339-148-17) and b) 100 case of 10 mL Unit Dose Cups (NDC 69339-148-19) Rx Only, Dash Pharmaceuticals, Upper Saddle River, NJ 07458.

Product Quantity:
45,940 Unit Dose Cups

Reason for Recall:
Labeling: Label Mix-Up

Recall Number:
D-0749-2022

Code Information:
Lot #: a) 376908P40, Exp. Date 02/28/2023; b) 376908P100, Exp. Date 02/28/2023

Class II Drugs Event

Event ID:
89864

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 10 mg/12.5 mg*, 90 Tablets bottles, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-3112-23.

Product Quantity:
53 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0754-2022

Code Information:
Lot FG5379; Exp. 08/2024

Product Description:
Accuretic (quinapril HCl/hydrochlorothiazide) Tablets 10 mg/12.5 mg 90 tablets bottle, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0222-23

Product Quantity:
160 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0755-2022

Code Information:
Lot EA6686; Exp. 04/2022

Product Description:
Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 20 mg/12.5 mg, 90 tablets bottles, Rx Only Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0220-23.

Product Quantity:
1364 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0756-2022

Code Information:
Lot EA6665, Exp Date 04/2022, Lot CN0640, Exp Date 04/2022

Product Description:
Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 20 mg/25 mg, 90 tablets bottles, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0223-23.

Product Quantity:
265 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0757-2022

Code Information:
Lot ET6974; Exp. 02/2023

Product Description:
quinapril and hydrochlorothiazide tablets, 20 mg/25 mg*, 90 Tablets bottles, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-5225-9

Product Quantity:
2442 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0758-2022

Code Information:
Lot FE3714; Exp. 02/2023

Product Description:
quinapril HCl/hydrochlorothiazide tablets, 20 mg/12.5 mg*, 90 Tablets bottles, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-0220-1

Product Quantity:
21108 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0759-2022

Code Information:
Lots DN6931, ED3904 & ED3905; Exp. 03/2023

Product Description:
quinapril HCl/hydrochlorothiazide tablets, 20 mg/25 mg*, 90 Tablets, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-0223-1

Product Quantity:
1104 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0760-2022

Code Information:
Lot DP3414; Exp 02/2023

Product Description:
Accuretic (quinapril HCl/hydrochlorothiazide) tablets, 20 mg/12.5 mg*, 90 Tablets, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc., NY. NY 10017, Made in Germany, NDC 0071-5212-23 .

Product Quantity:
195 bottles

Reason for Recall:
CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit.

Recall Number:
D-0761-2022

Code Information:
Lot FG5381; Exp. 08/2024

Class II Drugs Event

Event ID:
89873

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Revive Personal Products Company
2 Myrtle Ave
Allendale NJ United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
The Natural Dentist Healthy Breath Antiseptic Rinse, Cool Mint, 16.9 FL OZ (500 mL, Manufactured for Revive Personal Products Company, Madison, NJ 07940, UPC Code 714132000714.

Product Quantity:
6156 bottles

Reason for Recall:
Labeling; Label mix-up and Wrong Bar Code; back label incorrectly states active ingredient as Peppermint Oil and Sage Oil and has the wrong UPC

Recall Number:
D-0751-2022

Code Information:
Lot #: 3640A, Exp 12/22

Class II Drugs Event

Event ID:
89893

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MERCK SHARP & DOHME CORP
1 Merck Dr
Whitehouse Station NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Janumet (sitagliptin and metformin HCl) tablets, 50 mg/500 mg, 14-count bottle, packaged as 2 bottles per carton , Sample-Not For Sale, Rx Only, Manufactured for Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ 08889, USA, by Patheon Puerto Rico, Inc. Manati, Puerto Rico, 00674 Bottle (NDC 0006-0575-02), Carton (NDC 0006-0575-03)

Product Quantity:
3600 cartons

Reason for Recall:
Presence of foreign substance: Presence of stainless steel particulates in tablets.

Recall Number:
D-0746-2022

Code Information:
Lot: U015824, Exp. 09/22.

Class II Drugs Event

Event ID:
89906

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc
3711 Collins Ferry Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Travoprost Ophthalmic Solution, USP, 0.004%, 2.5 mL bottle, Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505, NDC 0378-9651-32.

Product Quantity:
20,112 bottles

Reason for Recall:
Subpotent Drug and Failed Impurities/Degradation Specifications: low out-of-specification results obtained for assay and high out-of-specification results for related substance impurities/degradation during routine stability testing.

Recall Number:
D-0748-2022

Code Information:
Lot # TV11W101, Exp Mar 2023

Class III Drugs Event

Event ID:
89766

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/07/2022

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:
USA Nationwide

Associated Products

Product Description:
Risedronate Sodium Tablets, USP, 5 mg, Rx Only, 30-count bottle, Manufactured for: Macleods Pharma USA, Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., BAddi, HImchal Pradesh, INDIA, NDC 33342-107-07.

Product Quantity:
4872 bottles

Reason for Recall:
FAILED CONTENT UNIFORMITY SPECIFICATIONS

Recall Number:
D-0762-2022

Code Information:
Lot #: BRD2001A, Exp 5/2022

Class III Drugs Event

Event ID:
89885

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Accelerator Applications USA, Inc.
57 E Willow St
Millburn NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
NETSPOT (kit for the preparation of Ga 68 dotatate injection) 40 mcg dotatate, kit contains Vial 1 (Reaction vial with lyophilized powder), 1 Single dose vial, consisting of 40 mcg of dotate, 5 mcg of 1,10-phenanthroline, 6 mcg of Gentisic acid, 20 mg of D-Mannitol, and Nitrogen; and Vial 2, 1 Single dose vial of reaction buffer, Rx Only, Manufactured for: Advanced Accelerator Applications USA, Inc., by: Gipharma S.r.l., Strada Crescentino snc, 13040 Saluggia (Vc), Italy, NDC 69488-001-40

Product Quantity:
14,089 kits

Reason for Recall:
Subpotent Drug: low out-of-specification results for Vial 1 assay obtained during stability studies.

Recall Number:
D-0747-2022

Code Information:
Lot # (Vial 1)/kit: (F03221004 vial) in kit PG1921014, PG1921015, Exp 16-Mar-2022; (F03221005 vial) in kit PG1921016, PG1921017, Exp 18-Mar-2022; (F03221006 vial) in kit PG1921018, PG1921019, Exp 11-May-2022; (F03221007 vial) in kit PG1921020, PG1921021, Exp 04-Aug-2022

Class III Drugs Event

Event ID:
89923

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/06/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Methylprednisolone Tablets, USP 4mg, 100-count bottle, Rx Only, Manufactured by: Jubliant Cadista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-001-06

Product Quantity:
19,222 Bottles (100-count)

Reason for Recall:
Subpotent

Recall Number:
D-0752-2022

Code Information:
Lot # 21 P0322, Exp. 01/2023

Class III Drugs Event

Event ID:
89937

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Ritedose Corporation
1 Technology Cir
Columbia SC United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
23.4% Sodium Chloride Injection, 120 mEq per 30 mL (4 mEq/mL), 50 mL prefilled syring, Rx Only, RITEDOSE, 503B Outsourcing Facility, A Division of the RITEDOSE Corporation, 1 Technology Circle, Columbia, SC 29203, 1-866-994-4670, NDC: 65302-509-30, barcode N (01) 003 65302 50930 0

Product Quantity:
3795 syringes

Reason for Recall:
Labeling: Incorrect Barcode: Product barcode incorrectly identifies the product as rocuronium bromide injection 100 mg per 10 mL instead of sodium chloride injection 23.4%, 120 mEq per 30 mL.

Recall Number:
D-0745-2022

Code Information:
Lots: 210137-01 BUD: 05/25/2022; 220026-01 BUD: 8/12/2022; 220050-01 BUD: 08/22/2022

Not Yet Classified Drugs Event

Event ID:
89917

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Cequa (cyclosporine ophthalmic solution) 0.09%, 6 pouches x 10 single-use vials (0.25 mL each) per carton, Rx only, Distributed by: Sun Pharmaceuticals Industries Inc., Cranbury, NJ 08512, NDC 47335-506-96.

Product Quantity:
73,030 cartons

Reason for Recall:
Subpotent Drug and Presence of Particulate Matter: low out-of-specification results obtained for assay and the presence of particulate matter.

Recall Number:

Code Information:
Lot: 10014, 10016, Exp 08/2022