Enforcement Report - Week of November 2, 2022

Class I Drugs Event

Event ID:
90909

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Atenolol Tablets, USP, 25 mg, 1000-count bottle, Rx only, Manufactured by: ALPHAPHARM PTY LTD, Marketed by: GSMS, Incorporated, Camarillo, CA 93012, USA, NDC 60429-027-10

Product Quantity:
2,584 Bottles

Reason for Recall:
Label Mix - up; a bottle labeled as Atenolol 25mg Tablets contained Clopidogrel 75mg Tablets

Recall Number:
D-0019-2023

Code Information:
Lot #: GS046745, Exp 12/2023

Class I Drugs Event

Event ID:
90956

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/27/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) 50 mL Single Dose Vials, packaged in cartons of 20 vials, Rx only, Manufactured and Distributed by: Exela Pharma Sciences, LLC Lenoir, NC 28645. Carton NDC 51754-5001-5, vial NDC 51754-5001-1

Product Quantity:
2,123,040 vials

Reason for Recall:
Defective Container: Complaints received of vial breakage and glass flying when pressurized while preparing the product for administration

Recall Number:
D-0022-2023

Code Information:
Lot # : P0001370, P0001371, P0001372, Exp. 10/2023; P0001433, P0001434 Exp. 11/2023; P0001443, P0001468, P0001469, P0001470, P0001495, P0001505, P0001506, P0001509, P0001510, P0001511, P0001512 Exp. 12/2023; P0001560, P0001561, P0001562, P0001564, P0001566, P0001567, P0001568 Exp. 01/2024; P0001571, P0001572, P0001573, P0001574, P0001578, P0001579, P0001580, P0001583, P0001586, P0001587, P0001588, P0001593, P0001594, P0001610, P0001618, P0001619, P0001654 Exp. 02/2024; P0001644, P0001645, P0001646, P0001662, P0001664 Exp. 03/2024; P0001730 Exp. 05/2024.

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) 50 mL Single Dose Vials, packaged in cartons of 20 vials, Rx Only, Mfd for: Civica, Inc. Lehi, Utah 84043, Mfd by: Exela Pharma Sciences, LLC, Lenoir, NC 28645, Carton NDC 72572-740-20, vial NDC 72572-740-1.

Product Quantity:
148,920

Reason for Recall:
Defective Container: Complaints received of vial breakage and glass flying when pressurized while preparing the product for administration

Recall Number:
D-0023-2023

Code Information:
Lot #: P0001497 Exp. 12/2023; P0001600 Exp. 02/2024; P0001663 Exp. 03/2024

Class II Drugs Event

Event ID:
90925

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/30/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/24/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fondaparinux Sodium Injection, USP, 7.5 mg per 0.6 mL, Single Dose, Prefilled Syringe, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520. Made in India. NDC 55150-232-10 (carton)NDC 55150-232-00 (syringe)

Product Quantity:
11,520 units

Reason for Recall:
Subpotent Drug: Out of specification for assay

Recall Number:
D-0020-2023

Code Information:
Lot # CFN200020, EXP Nov. 2022

Class II Drugs Event

Event ID:
90943

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/30/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Pyridostigmine Bromide Oral Solution, USP 60 mg/5 mL Delivers 5 mL, packaged in 5mL unit-dose cup, Rx only, Dist. by: VistaPharm, NDC 66689-406-01

Product Quantity:
1980 cups

Reason for Recall:
cGMP Deviations: Out of specification for assay of one of the preservative ingredients.

Recall Number:
D-0018-2023

Code Information:
Lot#: 832400, Exp 08/2023

Class II Drugs Event

Event ID:
90949

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/26/2022

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

Associated Products

Product Description:
Quinapril and Hydrochlorothiazide Tablets, USP 20mg/12.5mg, 90 Tablets bottles Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520, Made in India, NDC 65862-162-90

Product Quantity:
9504 bottles

Reason for Recall:
CGMP Deviations: Detection of N-Nitroso-quinapril impurity above the acceptable daily intake limit.

Recall Number:
D-0021-2023

Code Information:
Lots QE2021005-A and QE2021010-A, exp 01/2023

Class II Drugs Event

Event ID:
90973

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/15/2022

Voluntary / Mandated:

Center Classification Date:
10/21/2022

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ultra Chem Labs Corp
4581 Brickell Privado St
Ontario CA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Proton Armor, Anti-Microbial Alcohol-Free Foaming Hand Sanitizer, kills 99.99% of germs, Odor Free, Family Safe, No Gels, Water Based, 24 Hour Germ Protection with Moisturizers for Sensitive Skin, a) 8 oz bottle, b) 32 oz bottle and c) 1.7 fl oz or 50 mL bottle, Supplier details: Ultra Chem Labs, Ontario, CA, Active Ingredients - Benzalkonium Chloride 0.13% (antimicrobial), ULS 8357 0.33% (antimicrobial shield), NDC 79208-001-50.

Product Quantity:
5-10 gallons

Reason for Recall:
Chemical Contamination and CGMP Deviations: trace amounts of methanol found in one of the components during the manufacturing process.

Recall Number:
D-0016-2023

Code Information:
Batch: 20087131. No Expiration dates Product Code: a) 3020-8 (8 oz) b) 3020-3 (32 oz) c) 3020-5 (1.7 fl oz./50 mL)

Product Description:
Proton Armor, Anti-Microbial Alcohol-Free Foaming Hand Sanitizer, kills 99.99% of germs, Green Tea and Aloe, Family Safe, No Gels, Water Based, 24 Hour Germ Protection with Moisturizers for Sensitive Skin, a) 8 oz bottle, b) 32 oz bottle, and c) 1.7 fl oz or 50 mL bottle, Supplier details: Ultra Chem Labs, Ontario, CA, Active Ingredients - Benzalkonium Chloride 0.13% (antimicrobial), ULS 8357 0.33% (antimicrobial shield), NDC 79208-001-50.

Product Quantity:
5-10 gallons

Reason for Recall:
Chemical Contamination and CGMP Deviations: trace amounts of methanol found in one of the components during the manufacturing process.

Recall Number:
D-0017-2023

Code Information:
Batch 20117206. No Expiration dates Product Code: a) 3030-8 (8 oz) b) 3030-3 (32 oz) c) 3030-5 (1.7 fl oz./50 mL)