Enforcement Report - Week of March 15, 2023

Class I Drugs Event

Event ID:
91707

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/10/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Pharmedica USA, LLC
2836 W Deer Valley Rd Bldg E2
Phoenix AZ United States

Distribution Pattern:
Nationwide in the USA and Worldwide through e-commerce and trade shows

Associated Products

Product Description:
Purely Soothing 15% MSM Drops, packaged in a)15 ml, .5 fl oz bottle, UPC 7 31034 91382 9; and b) 30 ml, 1.014 fl oz bottle, UPC 7 31034 91379 9; Manufactured by: Pharmedica USA, Phoenix, AZ.

Product Quantity:
a) 869 bottles; b) 1035 bottles

Reason for Recall:
Non-Sterility

Recall Number:
D-0456-2023

Code Information:
Lot #s: a) 1808051, Exp.: 01/01/2027; b) 2203PS01, Exp.: 01/01/2027

Class I Drugs Event

Event ID:
91714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/09/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nanomaterials Discovery Corporation
14419 Greenwood Ave N Suite A, #424
Seattle WA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Snowy Range Blue Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution, 4fl. oz. [118mL], Distributed by Reliable Products, LLC, Cheyenne, WY 82003, NDC 75288-100-04.

Product Quantity:
500 bottles

Reason for Recall:
Chemical Contamination: FDA analysis found the product to contain methanol, acetaldehyde, and acetal above the limits.

Recall Number:
D-0455-2023

Code Information:
All Lots

Class II Drugs Event

Event ID:
91670

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/06/2023

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 in the USA

Associated Products

Product Description:
Verapamil Hydrochloride Extended-Release Tablets, USP, 120 mg, Rx Only, 100 Tablets per Carton (10 x 10), Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-493-01; NDC Unit Dose: 60687-493-11.

Product Quantity:
422 cartons

Reason for Recall:
Failed Dissolution Specification: Out of specification dissolution results at time point zero. The OOS was above specified values.

Recall Number:
D-0436-2023

Code Information:
Lot 1009065, Exp 12/31/2023

Class II Drugs Event

Event ID:
91707

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/10/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Pharmedica USA, LLC
2836 W Deer Valley Rd Bldg E2
Phoenix AZ United States

Distribution Pattern:
Nationwide in the USA and Worldwide through e-commerce and trade shows

Associated Products

Product Description:
Purely Soothing MSM Nasal Spray, 15%, packaged in 30ml, 1.014 fl. oz bottles, Manufactured by: Pharmedica USA, Phoenix, AZ, UPC 7 31034 91380 5

Product Quantity:
995 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0457-2023

Code Information:
Lot #: 1808051, Exp.: 01/01/2027

Class II Drugs Event

Event ID:
91708

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nutraceutical Corporation
1777 Sun Peak Dr
Park City UT United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
NaturalCare bioAllers, Allergy Nasal Spray, Homeopathic, All Region Formula, 0.8 fl oz(24mL), Mfd. Nutraceutical Corp., NaturalCare Park City, UT, 84098 USA, UPC 3 71400 70801 9

Product Quantity:
13,974

Reason for Recall:
CGMP Deviations: Raw material recalled by repackager, due to discoloration.

Recall Number:
D-0437-2023

Code Information:
Lot: 221263, Exp: 10/24; 222047, 222048 Exp: 02/25; 222099, 222100, Exp: 03/25

Product Description:
NatraBio, Cold& Sinus Nasal Spray, Homeopathic Medicine, 0.8 FL Oz. (24ml), Mfd. for Healthway Corp. Comments or Questions NatraBio Shelburne Falls, MA 01370 USA, UPC 3 71400 55711 2

Product Quantity:
4004

Reason for Recall:
CGMP Deviations: Raw material recalled by repackager, due to discoloration.

Recall Number:
D-0438-2023

Code Information:
Lot: 222016, Exp: 01/25;

Product Description:
NaturalCare bioAllers, Mold, Yeast and Dust, Homeopathic, Liquid Drops, 20% Alcohol, 1 FL OZ(30mL), Mfd. for Nutraceutical Corp. NaturalCare Park City, UT, 84098 USA

Product Quantity:
8,146

Reason for Recall:
CGMP Deviations: Raw material recalled by repackager, due to discoloration.

Recall Number:
D-0439-2023

Code Information:
Lot 222076, Exp: 03/27;

Product Description:
NaturalCare, children's, Allergy Care, Homeopathic, 4 Months and Up, Liquid Drops, 0.1% Alcohol, 1 FL OZ(30mL), Mfd. Nutraceutical Corp., Salt Lake City, UT, 84101 USA, UPC 3 71402 30101 0

Product Quantity:
1590

Reason for Recall:
CGMP Deviations: Raw material recalled by repackager, due to discoloration.

Recall Number:
D-0440-2023

Code Information:
Lot 222148, Exp: 05/25;

Class II Drugs Event

Event ID:
91719

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ecometics, Inc.
19 Concord St
Norwalk CT United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Alcolado Relampago (menthol 1%, camphor 1.5%), packaged in a) 7 fluid oz. (207 ml) and b) 16 fluid oz. (472 ml) bottles, Distributed by: The Larkspur Group Inc. South Norwalk, CT 06854

Product Quantity:
18,000 bottles

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0446-2023

Code Information:
Lot #: a) and b) 2E018A, 2E021A, 2E286A, Exp. date Jan-25

Product Description:
Vencedor medicated balm (capsaicin 0.028%) 1.5 oz. (43g) tubes, Distributed by: The Larkspur Group Inc. Norwalk, CT 06854

Product Quantity:
4,210 metal tubes/folding carton

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0447-2023

Code Information:
Lot #: 2E021A, Exp. Date Jan-25

Product Description:
Unguentine Original Ointment for Burns (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Oxide 6.6%) packaged in 1 oz. (28g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756

Product Quantity:
20,746 metal tubes/folding cartons

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0448-2023

Code Information:
Lot # 2E116A, Exp. Date APR-24

Product Description:
Soltice Quick-RUB (Menthol 5.1%, Camphor 5.1%) packaged in a) 1.33 oz (37g) plastic jars and b) 3 Oz (85g) plastic jars

Product Quantity:
a) 23,993 plastic jar/folding carton and b) 34,284 plastic jar/folding carton

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0449-2023

Code Information:
Lot #: a) 0E344A /AA, exp. date N/A; b) 2E243A, Exp. Aug-25

Product Description:
Nose Better Gel (0.75% Camphor, 0.50% Menthol, 0.50% Allantoin), packaged in 0.46 oz. (13g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756

Product Quantity:
37,968 metal tube/folding carton

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0450-2023

Code Information:
Lot #: 1E253A, Exp. Date AUG-2024

Product Description:
Activator Concentrate (sodium fluoride 0.96% in Activator) 1 fl. Oz, liquid oral rinse plastic bottles, Manufactured for: All USA Direct LLC, Broadview, IL 60155

Product Quantity:
34,320 bottles

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0451-2023

Code Information:
Lot #: 2E055A, Exp. Date Feb-2025

Product Description:
Unguentine Original Maximum Strength Pain Relieving/Antiseptic Ointment (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Oxide 6.6%), packaged in 1 oz. (28.3g) metal tubes, Distributed by: Oakhurst Company Levittown, NY 11756

Product Quantity:

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0452-2023

Code Information:
Lot #: 1E346A, Exp. Date Nov-23; 2E304A, Exp. Date Oct-24

Class II Drugs Event

Event ID:
91744

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States

Distribution Pattern:
CA

Associated Products

Product Description:
Metformin hydrochloride Extended-Release Tablets, 1000 mg, 60-count bottle, RX only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314 USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA, NDC 00591-2720-60

Product Quantity:

12,044 Bottles

Reason for Recall:
CGMP Deviations: Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.

Recall Number:
D-0441-2023

Code Information:
Lot #: 1410946A; Exp. 06/2023

Class II Drugs Event

Event ID:
91762

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/21/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood CO United States

Distribution Pattern:
Nationwide within the United States including VA or other Government facilities

Associated Products

Product Description:
Phenylephrine HCl 0.5 mg per 5 mL (100 mcg/mL), 5 mL Syringe, Rx only, Leiters 13796 Compark Blvd Englewood CO 80112, NDC 71449-001-11

Product Quantity:
13,445 units

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0442-2023

Code Information:
Lot #: 2230960, Exp date 3/12/2023; 2231080, Exp date 4/9/2023.

Product Description:
Phenylephrine HCl 1mg per 10mL (100 mcg/mL) 10 mL syringes, Rx only, Leiters 13796 Compark Blvd Englewood CO 80112, NDC 71449-001-15

Product Quantity:
325,300 units

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0443-2023

Code Information:
Lot #: 2230895, Exp. Date 3/5/2023; 2230911, Exp. Date 3/11/2023; 2230913, Exp. Date 3/18/2023; 2230994, Exp. Date 3/27/2023; 2231006, Exp. Date 4/1/2023; 2231109, Exp. Date 4/19/2023; 2231126, Exp. Date 5/6/2023; 2231134, Exp. Date 5/10/2023; 2231140, Exp. Date 5/14/2023; 2231142, Exp. Date 5/20/2023; 2231156, Exp. Date 5/29/2023; 2231273, Exp. Date 6/3/2023; 2231285, Exp. Date 6/10/2023; 2231299, Exp. Date 6/17/2023; 2231331, Exp. Date 6/26/2023; 2330014, Exp. Date 7/9/2023; 2330025, Exp. Date 7/15/2023

Product Description:
Phenylephrine HCl 40 mg (160 mcg/mL) added to 0.9% Sodium Chloride 250 mL IV Bag, Leiter Compounding Health 13796 Compark Blvd

Englewood CO 80112, NDC 71449-150-82

Product Quantity:
1212 units

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0444-2023

Code Information:
Lot #: 2231017, Exp. Date 3/12/2023

Product Description:
Phenylephrine HCl 20 mg (80 mcg/mL) added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health 13796 Compark Blvd Englewood CO 80112, NDC 71449-148-94

Product Quantity:
8,136 units

Reason for Recall:
CGMP DEVIATIONS

Recall Number:
D-0445-2023

Code Information:
Lot #: 2231026, Exp. Date 2/23/2023; 2231051, Exp. Date 3/11/2023; 2231156, Exp. Date 5/29/2023; 2231163, Exp. Date 3/26/2023; 223130, Exp. Date 4 5/7/2023; 2231308, Exp. Date 5/11/2023

Class II Drugs Event

Event ID:
91769

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2023

Voluntary / Mandated:

Center Classification Date:
03/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 Mcgaw Ave
Irvine CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Heparin Sodium, 25,000USP units per 250 mL, (100 USP units per mL) in 5% Dextrose Injection, 250 mL Excel Container, B.Braun Medical Inc, Bethlehem, PA. 18018-3524 USA. NDC 0264-9587-20.

Product Quantity:
30672

Reason for Recall:
Superpotent Drug: low Anti-Factor IIa potency.

Recall Number:
D-0434-2023

Code Information:
Lot J2C017; Expiration: 9/30/2023.

Class II Drugs Event

Event ID:
91789

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/06/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sagent Pharmaceuticals Inc
1901 N Roselle Rd Ste 450
Schaumburg IL United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Heparin Sodium Injection, USP, 20,000 USP units per mL, 25 x 1 mL Multi-Dose Vials, Rx Only, For Intravenous or Subcutaneous Use, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195; Made in India, NDC carton: 25021-404-01

Product Quantity:
28,875 vials

Reason for Recall:
Labeling: Not elsewhere classified

Recall Number:
D-0435-2023

Code Information:
Lot#: WP201, Exp 2/2024

Class II Drugs Event

Event ID:
91803

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/03/2023

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Brimonidine Tartrate Ophthalmic Solution 0.15%, Rx Only, Packaged as: a) 5 mL dropper bottle, NDC 60505-0564-1, UPC 3 60505 05641 5; b) 10 mL dropper bottle NDC 60505-0564-2, UPC 3 60505 05642 2; c) 15 mL dropper bottle, NDC 60505-0564-3, UPC 3 60505 05643 9; Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, FL 33326

Product Quantity:
67,056 bottles

Reason for Recall:
Lack of sterility assurance: Cracks have developed in some of the units caps of Brimonidine tartrate ophthalmic solution bottles. There is a possibility the broken cap may impact sterility.

Recall Number:
D-0433-2023

Code Information:
Lots: a) TJ9848 Exp. 02/2024, TJ9849 Exp. 02/2024, TK0258 Exp. 04/2024, TK5341 Exp. 04/2024; b) TK0261 Exp. 04/2024; c) TK0262 Exp. 04/2024

Class III Drugs Event

Event ID:
91785

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/09/2023

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:
Nationwide within the United States

Associated Products

Product Description:
DIBUCAINE 1% HEMORRHOIDAL OINTMENT, 1 oz. (28 gm), Manufactured for: Akron Pharma Inc. Fairfield NJ 07004, NDC 71399-2829-1

Product Quantity:
4,416 tubes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date

Recall Number:
D-0454-2023

Code Information:
Lot #: 2206016, Exp. date 05/2024