Enforcement Report - Week of June 5, 2024

Class I Drugs Event

Event ID:
94550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Revive Rx LLC dba Revive Rx Pharmacy
3831 Golf Dr Ste A
Houston, TX 77018-5218
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Tirzepatide 10 mg/0.5 mL Sterile Solution, 2 mL Multi-dose vial, Rx only, This is a Compounded Product By: Revive RX Pharmacy, 3831 Golf Dr A, Houston, TX 77018, internally assigned NDC 99000-9278-64

Product Quantity:
751 vials

Reason for Recall:
Labeling: Label Mix-up - product labeled as tirzepatide contains testosterone cypionate

Recall Number:
D-0511-2024

Code Information:
Lot #: 748127, Exp 9/24/2024

Class II Drugs Event

Event ID:
94354

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/30/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ARG Laboratories, Inc.
2639 Manana Dr
Dallas, TX 75220-1301
United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Bottle with pump, NET WT 16 fluid oz / 473.17 ml, Made in USA, www.painwizard.com Pain Wizard LLC.PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00012 3

Product Quantity:
3,440

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0520-2024

Code Information:
Lot: 18723C3, Exp 06/30/2025

Product Description:
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%) Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Gallon Jug 128 fl. oz. (3776 ml), Manufactured for Golden Tiger LLC, Made in USA, UPC 1 82294 00005 5

Product Quantity:
192

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0521-2024

Code Information:
Lot: 01823C2, Exp 01/31/2025

Product Description:
Bull Frog SPF 50 Amphibious Lotion SPF 50 Amphibious Lotion with Water Armor Tech, Broad Spectrum Sunscreen with UVA/UVB Protection, NEW WT. 5 FL OZ (148ML), Distributed by: Bullfrog Brands LLC, PO Box 600207, Dallas, TX 75360 USA. UPC 8 50016 52112 5

Product Quantity:
9,697

Reason for Recall:
Out of Specification for active ingredient

Recall Number:
D-0522-2024

Code Information:
Lot 08623C2, 08923C2, Exp 03/31/2026

Product Description:
ALOE GATOR, (Octocrylene 8%, Octyl Methoxycinnamate 6%, Benzophone 3 6%, Octyl Salicylate 5%), Original Formula, SPF 40+, Broad Spectrum Protective Gel, Sport Performance, NET WT 1 OZ (28 g), Manufactured for AGS Brands.

Product Quantity:
4,013

Reason for Recall:
Out of Specification for active ingredient

Recall Number:
D-0523-2024

Code Information:
Lot 04023C1, Exp 01/31/2025

Product Description:
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Tube, NET WT 8 oz (226.79g), Made in the USA, painwizard.com PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00011 6

Product Quantity:
7,410

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0524-2024

Code Information:
Lots 19823C4, EXP 07/31/2025; 01623C1, Exp 01/31/2025

Product Description:
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Tube, NET WT 4oz (113.39g), painwizard.com Made in the USA, PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00019 2

Product Quantity:
2,864

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0525-2024

Code Information:
Lot , 06023C1, Exp 01/31/2025,

Product Description:
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Pump Capsaicin, Aloe Vera, Willow Bark & MSM, Bottle with Pump NET WT 32 fl. oz (946.33ml), Manufactured for Golden Tiger LLC Made in USA, UPC 1 82294 00004 8

Product Quantity:
500

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0526-2024

Code Information:
Lot 01823C2, 01823C1, Exp 01/31/2025

Product Description:
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Tube 4 oz (113.39 g), Mfr. for Golden Tiger USA Albuq, NM, UPC 1 82294 00002 4

Product Quantity:
3,000

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0527-2024

Code Information:
Lot 01623C1, Exp 01/31/2025

Product Description:
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Roll-On 3 fl oz (88.7ml), painwizard.com Made in the USA, PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00010 9

Product Quantity:
3,504

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:

D-0528-2024

Code Information:
Lot 17323C3, Exp 06/30/2025

Product Description:
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Roll-On NET WT 3 fl. oz. (88.7ml), Manufactured for Golden Tiger USA Albuquerque, NM, UPC 1 82294 00006 2

Product Quantity:
1,680

Reason for Recall:
Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.

Recall Number:
D-0529-2024

Code Information:
Lot 17323C3, Exp 06/30/2025

Product Description:
ALOE GATOR, (Octocrylene 8%, Octyl Methoxycinnamate 6%, Benzophone 3 6%, Octyl Salicylate 5%), SPF 40+, Broad Spectrum Protective Gel, Sport Performance, NET WT 4 OZ (113g), Manufactured for AGS Brands. UPC 0 17971 10421 7

Product Quantity:
6,264

Reason for Recall:
Out of Specification for active ingredient

Recall Number:
D-0530-2024

Code Information:
Lot 04023C1 Exp 01/31/2025

Class II Drugs Event

Event ID:
94542

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Rubicon Research Private Limited
4 & K30 5 Plot No K - 30 District
Ambarnath
India

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Metoprolol Tartrate Tablets USP, 25mg, 1000 count bottle, Rx only, distributed by: TruPharma, LLC, Tampa, FL 33609, Manufactured by: Rubicon Research Private Limited, Ambernath Dist Thane 421506 India, NDC 52817-360-00

Product Quantity:
11,664 Bottles

Reason for Recall:
Presence of Foreign Substance: metal in tablet

Recall Number:
D-0517-2024

Code Information:
Lot 231037H1, exp 6/2027

Class II Drugs Event

Event ID:
94551

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Epinephrine-Lidocaine HCl 0.25 mg/mL and 7.5 mg/mL Preservative-Free 1mL Single-Use vials for Intraocular Injection, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-640-01

Product Quantity:
14,180 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0512-2024

Code Information:
Lot #: 23APR033, Exp. Date 5/1/24; 23JUN001, Exp. Date 6/5/24

Product Description:
Dexamethasone-Moxifloxacin (1 mg/mL and 5mg/mL) Preservative-Free, 1mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-512-01

Product Quantity:
39,700 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0513-2024

Code Information:
Lot #: 23MAY016, Exp. Date 5/8/24; 23JUL016, Exp. Date 7/10/24; 23AUG034, Exp. Date 8/16/24; 23DEC014, Exp. Date 12/10/24

Product Description:
Dexamethasone-Moxifloxacin- Ketorolac (1mg/mL, 0.5 mg/mL and 0.4 mg/mL), Preservative-Free, 1mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-513-01

Product Quantity:
38,060 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0514-2024

Code Information:
Lot #: 23MAY008, Exp. Date 5/1/24; 23OCT011, Exp. Date 10/26/24; 23NOV035, Exp. Date 12/6/24; 24JAN024, Exp. Date 1/14/25

Product Description:
Moxifloxacin 0.8 mg/0.8 mL Preservative-Free 0.8mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-509-08

Product Quantity:
18,980 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0515-2024

Code Information:
Lot #: 23OCT013, Exp. Date 10/10/2024

Product Description:
Moxifloxacin 4 mg/0.8 mL Preservative-Free 0.8mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-511-08

Product Quantity:
165,920 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0516-2024

Code Information:
Lot #: 23JUN003, Exp. Date 5/29/2024; 23JUL035, Exp. Date 7/24/2024; 23AUG033, Exp. Date 8/14/2024; 23AUG043, Exp. Date 8/21/2024; 23SEP001, Exp. Date 9/26/2024; 23OCT002, Exp. Date 10/4/2024; 23OCT031, Exp. Date 10/31/2024; 23NOV011, Exp. Date 11/28/2024; 24FEB027, Exp. Date 2/15/2025

Class II Drugs Event

Event ID:
94553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/30/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood, NJ 07852-9720
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Epinephrine-Lidocaine HCl 0.25 mg/mL and 7.5 mg/mL Preservative-Free 1mL Single-Use vial for Intraocular Injection, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-640-01

Product Quantity:
74,440 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0519-2024

Code Information:
Lot #: 23JUL025, Exp. Date 7/17/2024; 23SEP012, Exp. Date 7/11/2024; 23OCT015, Exp. Date 7/20/2024; 23OCT020, Exp. Date 7/25/2024; 23OCT026, Exp. Date 8/22/2024; 23NOV030, Exp. Date 8/29/2024, 23DEC026, Exp. Date 9/29/2024; 24JAN011, Exp. Date 7/21/2024; 24FEB033, Exp. Date 8/24/2024; 24JAN050, Exp. Date 8/30/2024

Class II Drugs Event

Event ID:
94602

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/08/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore, MD 21202-6174
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Cefdinir for Oral Suspension USP, 250 mg/5 mL, packaged in a 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, Manufactured by: Lupin Limited, Mandideep, 462 046 India, NDC 68180-723-04

Product Quantity:
51,006 bottles

Reason for Recall:
Defective container: lack of seal integrity.

Recall Number:
D-0518-2024

Code Information:
Lot #F305184, F305185, F305186, Exp 7/31/ 2025

Class II Drugs Event

Event ID:
94646

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/15/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/30/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Regeneron Pharmaceuticals Inc
777 Old Saw Mill River Rd
Tarrytown, NY 10591-6717
United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
EYLEA, (aflibercept) Injection, For Intravitreal injection, 2 mg (0.05mL of a 40mg/mL solution), Single-dose Pre-filled Glass Syringe, Rx only, Manufactured by: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, NDC 61755-005-01, NDC (sample lot) 61755-005-54

Product Quantity:
405,725 Prefilled syringes

Reason for Recall:
Lack of Assurance of Sterility: Complaints of syringe breakage

Recall Number:
D-0531-2024

Code Information:
Lot # 8231500321, Exp. date Oct-24 8231500335, Exp. date Jan-25 8231500333, Exp. date Jan-25 8231500334, Exp. date Jan-25 8231500339, Exp. date Jan-25 8231500347, Exp. date Jan-25 8231500336, Exp. date Jan-25 8231500337, Exp. date Jan-25 8231500340, Exp. date Jan-25 8268700014 (sample lot) exp. date Jan-25

Class II Drugs Event

Event ID:
94653

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/20/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/24/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genentech, Inc.
1 Dna Way Bldg 5
South San Francisco, CA 94080-4918
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Cathflo activase (ALTEPLASE), 2mg vials, Rx only, Genentech Inc., South San Francisco, CA 94080, NDC 50242-041-64

Product Quantity:

Lot:3618858 = 105,759; Lot:3618873 =90,359

Reason for Recall:
Lack of Assurance of Sterility: Deformed stoppers observed during filling operations for Cathflo Activase.

Recall Number:
D-0509-2024

Code Information:
Lot #: 3618858, 3618873, Exp. Date 01/31/2026

Class II Drugs Event

Event ID:
94686

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/28/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton, NJ 08540-6623
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Zoledronic Acid Injection 5mg/100mL Sterile Solution, 100mL Single-Dose vials, Rx only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-688-52

Product Quantity:
13,880 vials

Reason for Recall:
Lack of Assurance of Sterility: Leaking vials

Recall Number:
D-0510-2024

Code Information:
Lot #: G3000010, Exp. Date 11/2025