Enforcement Report - Week of May 1, 2024

Class I Drugs Event

Event ID:
94265

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/22/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pyramids Wholesale Inc.
464 E 4th St
Los Angeles CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Spanish Fly 22K capsules, 2-count box, UPC 0 664979 979455

Product Quantity:
45 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0448-2024

Code Information:
All lots

Product Description:
Weiner Boner Honey, 12g packet, 100% Organic Formula.

Product Quantity:
19 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0449-2024

Code Information:
All lots

Product Description:
Flower Power, CBD infused Female Enhancement, 59 ml bottle, UPC 0 678741 351646.

Product Quantity:

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0450-2024

Code Information:
All lots

Product Description:
Samurai-X Honey 6800, UPC 2 56891 27553 3.

Product Quantity:

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0451-2024

Code Information:
All lots

Product Description:
Pink Pussycat Honey, net wt: 20gx12 sachets, UPC 7 918750 046557

Product Quantity:
149 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0452-2024

Code Information:
All Lots

Product Description:
GoHARD 25000, Male Sexual Enhancement, Honey, 100% Natural, UPC: N/A.

Product Quantity:
12 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0453-2024

Code Information:
All lots

Product Description:
libigrow RED DRAGON+, Maximum Strength Formula, 2 capsules per box, UPC 7 05105 83073 5.

Product Quantity:
7 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0454-2024

Code Information:
All lots

Product Description:
SILVERBACK XXX POWER MALE ENHANCEMENT, 2 fl. oz., UPC 8 700470 032762

Product Quantity:
7 pieces

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0455-2024

Code Information:
All lots

Product Description:
The GOAT SUBLINGUAL STRIP, MALE ENHANCEMENT, 2 Pack, Distributed by Hombres LLC, 130 Maccormick Ave, Suite 105, Costa Mesa, A, UPC 6 61631 26363 1.

Product Quantity:
10 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0456-2024

Code Information:
All lots

Product Description:
ALPHASTRIP MALE PERFORMANCE ENHANCER, The fastest acting sublingual, Serving Size (1 strip), Distributed by: GALT INT'L

Product Quantity:
4,351 pieces

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0457-2024

Code Information:
All lots

Product Description:
HONEY MANUKA BUNNY LOVE, 12g, All Natural Sexual Enhancement, UPC: N/A

Product Quantity:
19 boxes

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.

Recall Number:
D-0458-2024

Code Information:
All lots

Class I Drugs Event

Event ID:
94335

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Aruba Aloe Balm N.V.
Pitastraat 115
Oranjestad Aruba

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Alcoholada Gel, Pain Relieving Gel, 0.5% Lidocaine Hydrochloride, packaged in (a) 8.5 fl oz (251 mL) plastic bottle UPC 0 82252 03120 9 (b) 2.2 fl oz (65 mL) plastic bottle, UPC 0 82252 34030 1 , Manufactured in Aruba by Aruba Aloe Balm Inc., Pitastraat 115, Aruba, Dutch Caribbean.

Product Quantity:
9,625 bottles

Reason for Recall:
Chemical Contamination: Product manufactured with ethanol API that contains methanol

Recall Number:
D-0459-2024

Code Information:
Lot, expiry: (a) 25253, Exp 5/1/2024; 25976, Exp 8/11/2024; 26150, Exp 9/11/2024; 26473, Exp 11/25/2024; 26553, Exp 12/11/2024; 27318, Exp 5/10/2025; 27481, Exp 6/15/2025; 27660, Exp 7/15/2025; 27839, Exp 8/5/2025; 28121, Exp 10/7/2025; 28152, Exp 10/18/2025; 28355, Exp 12/17/2025; 28761, Exp 2/22/2026; 29088, Exp 4/1/2026; 29510, Exp 5/11/2026; 29558, Exp 5/13/2026; 29728, Exp 6/3/2026; 30339, Exp 9/13/2026; 30563, Exp 10/27/2026. (b) 25253, Exp 5/1/2024; 25976, Exp 8/11/2024; 26150, Exp 9/11/2024; 26553, Exp 12/11/2024; 26696, Exp 1/8/2025; 27318, Exp 5/10/2025; 27481, Exp 6/15/2025; 27660, Exp 7/15/2025; 27839, Exp 8/5/2025; 28281, Exp 11/30/2025; 28355, Exp 12/17/2025; 28761, Exp 2/22/2026; 29088, Exp 4/1/2026; 29728, Exp 6/3/2026; 30086, Exp 7/26/2026; 30339, Exp 9/13/2026; 30563, Exp 10/27/2026.

Product Description:
Aruba Aloe Hand Sanitizer Gel, 80% Alcohol, 12 fl oz (355 mL) plastic bottle, Manufactured in Aruba by Aruba Aloe Balm Inc., Pitastraat 115, Aruba, Dutch Caribbean. UPC 0 82252 03300 5

Product Quantity:
5299 bottles

Reason for Recall:
Chemical Contamination: Product manufactured with ethanol API that contains methanol

Recall Number:
D-0460-2024

Code Information:
Lot #: 25160, Exp 4/16/2024; 25344, Exp 5/20/2024, 25580, Exp 6/15/2024; 25828, Exp 7/28/2024; 26057, Exp 8/25/2024; 26195, Exp 9/18/2024; 26471, Exp 11/25/2024; 26754, Exp 1/20/2025; 26821, Exp 2/2/2025; 27005, Exp 3/11/2025; 27518, Exp 6/22/2025; 27927, Exp 8/26/2025; 28176, Exp 10/22/2025; 28392, Exp 12/31/2025.

Class I Drugs Event

Event ID:
94339

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
FA Online Inc
6520 180th St
Fresh Meadows NY United States

Distribution Pattern:
USA Nationwide. The product was sold via Amazon Market Place.

Associated Products

Product Description:

ForeverMen Natural Energy Boost Capsules, packaged in a box containing a 10-count blister card.

Product Quantity:
400 capsules

Reason for Recall:
Marketed Without an Approved NDA/ANDA: Product was found to contain undeclared sildenafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this unapproved drug.

Recall Number:
D-0470-2024

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
94289

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/24/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Cipla USA, Inc.
10 Independence Blvd
Warren NJ United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Ipratropium Bromide and Albuterol Sulfate Inhalation Solution USP, 0.5 mg & 3mg/3mL unit-dose vials, packaged in carton containing 30 vials (6 pouches of 5 - 3 mL vials), Rx only, Manufactured by: Cipla Ltd., Indore SEZ, Pithampur, India, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-173-53

Product Quantity:
59244/3ml FFS packs

Reason for Recall:
Short fill: Complaints received of less fill volume in respule and few drops of liquid observed in the intact pouch.

Recall Number:
D-0471-2024

Code Information:
Lot # IA30390, Exp 4/30/2025, IA30517, Exp 6/30/ 2025

Class II Drugs Event

Event ID:
94345

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
HONEYWELL INC
855 S Mint St
Charlotte NC United States

Distribution Pattern:
Nationwide USA, Canada

Associated Products

Product Description:
Eyesaline, Saline Eyewash Solution, Cartridge for Fendall 2000, Net contents: 7.9 gal per cartridge, Sperian Eye & Face Protection, Inc., 825 East Highway 151, Platteville, WI 53818. NDC: 0498-0631-37

Product Quantity:
10, 605 cartridges

Reason for Recall:
CGMP Deviations

Recall Number:
D-0461-2024

Code Information:
Manufacturer's Product Number/ Catalog Number: 32-002050-0000; Exp 06/21/2025

Class II Drugs Event

Event ID:
94440

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/25/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Twice-a-Day Dosage, 100 Capsules per bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ, 07430, Product of India, NDC 68462-562-01.

Product Quantity:
3,264 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0472-2024

Code Information:
Lot #: 17221312, Exp. 5/31/2024

Class II Drugs Event

Event ID:
94447

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/23/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/25/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
EPI Health, LLC
174 Meeting St Ste 200
Charleston SC United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Cloderm (clocortolone pivalate) Cream, 0.1%, Rx Only, For Topical Use Only, Net Wt 45g, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-804-90

Product Quantity:
18645 tubes

Reason for Recall:
CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

Recall Number:
D-0473-2024

Code Information:
lot SDFC- exp. 5/31/2024 lot TFBW- exp. 5/31/2025

Product Description:
minolira (minocycline hydrochloride) extended-release tablets, 105mg 30-count Bottle, Rx Only, Mfg by: Dr Reddy's Laboratories Limited, INDIA, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-101-30.

Product Quantity:
12808 bottles

Reason for Recall:
CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

Recall Number:
D-0474-2024

Code Information:
lot # T2300765- exp. 11/30/2025 lot# T2201702A-exp. 02/28/2025 lot# T2201699- exp. 2/28/2025 lot# T2201698- exp. 2/28/2025

Product Description:
minolira (minocycline hydrochloride) extended-release tablets, 135mg 30-count Bottle, Rx Only, Mfg by: Dr Reddy's Laboratories Limited, INDIA, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-102-30.

Product Quantity:
5664 bottles

Reason for Recall:
CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

Recall Number:
D-0475-2024

Code Information:
lot# T2201700- exp. 02/28/2025 lot# T2201701- exp. 02/28/2025

Class II Drugs Event

Event ID:
94461

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/19/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2024

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Nomax Inc
9735 Green Park Industrial Dr
Saint Louis MO United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
GloStrips, Fluorescein Sodium Ophthalmic Strips USP (0.6 mg Fluorescein), Rx Only, a) 100 strips per carton, NDC 51801-003-40; b) 300 strips per carton, NDC 51801-003-50, Nomax, Inc., St. Louis, MO 63123.

Product Quantity:
15,056 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.

Recall Number:
D-0462-2024

Code Information:
Lot #s: a) 14904, Exp. 06/30/2024; Lot 14938, Exp. 07/31/2024; b) Lot 14931, Exp. 06/30/2024

Product Description:
GloStrips, Fluorescein Sodium Ophthalmic Strips USP (1.0 mg Fluorescein), Rx Only, 100 Sterile Strips per carton, Nomax, Inc., St. Louis, MO 63123, NDC 51801-009-40.

Product Quantity:
6,960 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.

Recall Number:
D-0463-2024

Code Information:
Lot #: 14708, Exp. 04/30/2024.

Product Description:
FUL-GLO, Fluorescein Sodium Sterile Ophthalmic Strips USP (0.6 mg Fluorescein), 300 sterile strips per carton, Manufactured for: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-403-03.

Product Quantity:

4648 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.

Recall Number:
D-0464-2024

Code Information:
Lot 14842, Exp. 6/30/2024

Product Description:
FUL-GLO, Fluorescein Sodium Ophthalmic Strips USP 1 mg, 100 sterile strips per carton, Manufactured for: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-404-01.

Product Quantity:
15,444 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.

Recall Number:
D-0465-2024

Code Information:
Lot #: 14776, Exp. 05/31/2024.

Class III Drugs Event

Event ID:
94382

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/09/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/23/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Second Tokushima Factory, Otsuka Pharmaceutical Co., Ltd.
224-18 Kawauchi-Cho
Tokushima Japan

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Abilify (aripiprazole), 5 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-007-13

Product Quantity:
108,192/30 count bottles or 7 count blister packs

Reason for Recall:
Cross Contamination with Other Products

Recall Number:
D-0466-2024

Code Information:
Lot # AKS00623A, Exp 01/31/2026; AKS00322A, Exp 02/28/2025

Product Description:
Abilify (aripiprazole), 10 mg tablets, packaged in a) 30 count bottles (NDC 59148-008-13) and b) 7 count blister packs (NDC 59148-008-95), RX

only, Otsuka America Pharmaceutical, Inc.

Product Quantity:

Reason for Recall:
Cross Contamination with Other Products

Recall Number:
D-0467-2024

Code Information:
Lot #: a) ALS00422A, Exp 04/30/2025; ALS00523A, Exp 11/30/2025; b) 1K77YUD1H1A, Exp 11/30/2024

Product Description:
Abilify (aripiprazole), 15 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-009-13

Product Quantity:

Reason for Recall:
Cross Contamination with Other Products

Recall Number:
D-0468-2024

Code Information:
Lot # AMS00223A, Exp 07/31/2025

Product Description:
Abilify (aripiprazole), 30 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-011-13

Product Quantity:

Reason for Recall:
Cross Contamination with Other Products

Recall Number:
D-0469-2024

Code Information:
Lot # APS00423A, Exp 07/31/2025; APS00222A, Exp 11/30/2024