Enforcement Report - Week of July 17, 2024

Class I Drugs Event

Event ID:
94737

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SYNCHRONICITY SPA INC, DBA SUNTE
2411 Tech Center Ct Ste 104
Las Vegas, NV 89128-0805
United States

Distribution Pattern:
Distributed Nationwide in the USA and Queensland, Christchurch, Ontario, Quebec, Alberta, British Columbia Cayman Islands, Bermuda, France, Amsterdam, Hants, Dubai, Hong Kong, Singapore, Taiwan

Associated Products

Product Description:
suntegrity, (Zinc Oxide 15%) IMPECCABLE SKIN sunscreen foundation, BUFF, Broad Spectrum SPF30, Net WT 2OZ (56.7 g), Suntegrity Skincare, Las Vegas, NV 89128, NDC: 69949-152-01 UPC 854245006187

Product Quantity:
1,902 tubes

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Presence of Aspergillus Sydowii (Mold)

Recall Number:
D-0588-2024

Code Information:
Lot#: 115BU, Exp: 06/30/2025;

Class II Drugs Event

Product Description:
suntegrity, (Zinc Oxide 15%) IMPECCABLE SKIN sunscreen foundation, Multiple Shades, Broad Spectrum SPF30, Net WT 2OZ (56.7 g), Suntegrity Skincare, Las Vegas, NV 89128, a) NDC: 69949-151-01, UPC: 854245006170 - IVORY b) NDC: 69949-156-01, UPC: 854245006224 - NUDE c) NDC: 69949-152-01, UPC: 854245006187 - BUFF d) NDC: 69949-153-01, UPC: 854245006194 - SAND e) NDC: 69949-155-01, UPC: 854245006217 - BRONZE f) NDC: 69949-157-01, UPC: 854245006446 - MOCHA

Product Quantity:
8202 tubes

Reason for Recall:
CGMP Deviations

Recall Number:
D-0589-2024

Code Information:
Lot: a) 107IV, Exp: 04/30/2025 b) 107NU, Exp: 06/30/2025; 109NU, Exp: 10/31/2025 c) 117BU, Exp: 10/31/2025 d) 113SA, Exp: 06/30/2025; 114SA, Exp: 10/31/2025 e) 106BR, Exp: 04/30/2025; f) 101MO, Exp: 05/31/2025

Class II Drugs Event

Event ID:
94843

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/26/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/09/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Equibal Inc
63-65 Jersey Ave
Unionville, NY 10988
United States

Distribution Pattern:
Nationwide in the USA via internet sales.

Associated Products

Product Description:
Blemfree All Day Lotion (salicylic acid 0.5% w/w), packaged in a) 1 oz. 29 ML tube NDC:53228-003-01 b) 4 OZ 118ML plastic bottle, UPC 7 01450 90008 6, NDC # 53228-002-01, Equibal Labs, Inc

Product Quantity:
90/1 oz. tubes and 248/4 oz. bottles

Reason for Recall:
CGMP Deviations: Manufactured without following Current Good Manufacturing Practises.

Recall Number:
D-0591-2024

Code Information:
Lot # a) BF063221, exp. date 03/04/2025, BF097221, exp. date 04/07/2025, b) BF097221 exp date 04/07/2025

Class II Drugs Event

Event ID:
94846

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/17/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/06/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield, IL 60015-4625
United States

Distribution Pattern:
US Nationwide, Canada

Associated Products

Product Description:
Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose, For Intraperitoneal Administration Only, 6000 mL per bag, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA. NDC: 0941-0457-01

Product Quantity:
6,874 bags

Reason for Recall:
Lack of Assurance of Sterility: Potential presence of leaks originating from the Connector Assembly component.

Recall Number:
D-0587-2024

Code Information:
Lot R24B25FA; Exp. 2/28/2026

Class II Drugs Event

Event ID:
94891

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/08/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
buPROPion Hydrochloride Extended-release Tablets USP (XL) Once-Daily, 150 mg, 100 Tablets (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC: 60687-782-01.

Product Quantity:
2,484 cartons

Reason for Recall:
Failed Dissolution Specifications; the product is dissolving faster than the specified limits.

Recall Number:
D-0590-2024

Code Information:
Lot 1017343, Exp. 12/31/2025

Class II Drugs Event

Event ID:
94930

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/03/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
TAILSTORM HEALTH INC
158 S Kyrene Rd
Chandler, AZ 85226
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lidocaine HCL Injection, USP 2% 200mg/10mL (20mg/mL) and EPINEPHRINE HCl 1:200,000, 10 ml Single Dose Vial, Rx only, Compounded drug by Medivant Healthcare, 158 S Kyrene Rd, Chandler, AZ 85226, NDC 81483-0038-0, UPC 3 81483 00380 2

Product Quantity:
12,525 10 mL vials

Reason for Recall:
Subpotent Drug: reduced efficacy for epinephrine

Recall Number:
D-0594-2024

Code Information:
Lot Number: 2311003, Expiration Date: 11/13/2024

Class III Drugs Event

Event ID:
94854

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
06/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharma Holding, Inc.
2 Tower Center Blvd Ste 1401
East Brunswick, NJ 08816-1149
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Diflorasone Diacetate Ointment, USP, 0.05%, 60g tube, Rx only, Mfd. By: Lyne Laboratories, Inc., Brockton, MA 02301; Mfd. For: Rising Pharmaceuticals, Inc., East Brunswick, NJ 08816 NDC 64980-124-60

Product Quantity:
868 tubes

Reason for Recall:
Failed Impurities/Degradation Specifications: The impurity results at 12 months stability testing,did not conform to the specification limit.

Recall Number:
D-0599-2024

Code Information:
Lot #, DI2303B, Exp 12/31/2024

Class III Drugs Event

Event ID:
94912

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/02/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Verapamil Hydrochloride Injection, USP 5 mg / 2mL(2.5 mg/mL), packaged as (a) 25x2 mL Single-Dose Vial per carton, Vial NDC: 70710-1643-1; Carton NDC 70710-1643-7; (b) 5x2 mL Single-Dose Vial per carton, Vial NDC: 70710-1643-1; Carton NDC 70710-1643-5; Rx Only, Manufactured by: Zydus Lifesciences Ltd. Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA)Inc., Pennington, NJ 08534,

Product Quantity:
170,755 vials

Reason for Recall:
Cross contamination with other products.

Recall Number:
D-0592-2024

Code Information:
Lot# (a) Lots L300255, L300262, Exp Date 07/31/2025; (b)L300263, Exp Date 08/31/2025

Product Description:
Verapamil Hydrochloride Injection, USP 10 mg/4 mL (2.5 mg/mL), 5 x 4 mL Single-Dose Vial per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA)Inc., Pennington, NJ 08534, Vial NDC: 70710-1644-1, Carton NDC: 70710-1644-5.

Product Quantity:
8020 vials

Reason for Recall:
Cross contamination with other products.

Recall Number:
D-0593-2024

Code Information:
Lot L300269, Exp Date 07/31/2025

Class III Drugs Event

Event ID:
94922

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
07/02/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/10/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Micafungin for injection, USP, 100 mg/vial, Single-Dose Vial, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1725-01 (vial), NDC 70710-1725-06 (outer box).

Product Quantity:
12720 vials

Reason for Recall:
Cross contamination with other products

Recall Number:
D-0595-2024

Code Information:
Lot #: L300220, Exp. 05/31/2025.

Product Description:
Micafungin for injection, USP, 100 mg/vial, Single-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Vadodara, India, NDC 16714-301-01 (vial), NDC 16714-301-10 (outer box).

Product Quantity:
n/a

Reason for Recall:
Cross contamination with other products

Recall Number:
D-0596-2024

Code Information:
Lot #: L300217, Exp. 04/31/2025.