Enforcement Report - Week of December 13, 2023

Class I Drugs Event

Event ID:
93394

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/02/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
SUGARMDS LLC
11470 Schenk Dr
Maryland Heights MO United States

Distribution Pattern:
U.S. Nationwide and online websites.

Associated Products

Product Description:
Dr. Ergin's SugarMD, ADVANCED GLUCOSE SUPPORT Capsules, Dietary Supplement, helps support healthy glucose levels a) 60 count (UPC 1 95893 92767 8), b) 120 count (UPC 1 95893 54697 8), c) 180 count (UPC 1 95893 99957 6) bottles, Manufactured for SUGARMDS LLC, Port St. Lucie, FL 34952.

Product Quantity:
32,117

Reason for Recall:
MARKETED WITHOUT AN APPROVED NDA/ANDA: Product found to be tainted with metformin and glyburide

Recall Number:
D-0138-2024

Code Information:
LOT# 22165-003, EXP 09/30/2024

Class I Drugs Event

Event ID:
93464

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novartis Pharmaceuticals Corporation
1 Health Plz
East Hanover NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
SANDIMMUNE Oral Solution (cyclosporine oral solution, USP) 100 mg/mL, 50 mL bottle, Rx Only, Manufactured by: DELPHARM Huningue S.A.S., Huningue, France, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. NDC 0078-0110-22

Product Quantity:
6,997 bottles

Reason for Recall:
Crystallization: bottles of Sandimmune Oral Solution were determined to contain crystals

Recall Number:
D-0144-2024

Code Information:
Lot #: FX001500, FX001582, Exp. 09/30/2024

Class II Drugs Event

Event ID:
93345

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Padagis US LLC
3940 Quebec Ave N
Minneapolis MN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Trospium Chloride Extended-Release Capsules, 60 mg, 30 Capsules per bottle, Rx Only, Manufactured By: Sidmak Laboratories (India) Pvt. Ltd. Plot No. 20, Pharmacity, Selaqui Industrial Area, Dehradun-248 197 Uttarakhand, India Distributed By: Padagis, Allegan, MI 49010. NDC: 0574-0118-30

Product Quantity:
7,032 bottles

Reason for Recall:
Failed Tablets/Capsules specifications; missing/broken/extra tablets within the capsules

Recall Number:
D-0139-2024

Code Information:
Lot: 231104, 231105, 231106, exp 7/31/2025

Class II Drugs Event

Event ID:
93359

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Ondansetron Injection, USP, 4 mg/2 mL (2 mg/mL), 2 mL per vial, Rx only, Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015 USA. Manufactured by: Baxter Pharmaceuticals India Private Ltd, Ahmedabad 382213, India. NDC 36000-012-25

Product Quantity:
6,022,675 vials

Reason for Recall:
Failed pH Specifications

Recall Number:
D-0146-2024

Code Information:
Lot # A0E0959A, A0E0961A, A0E1015A, A0E1020A, Exp. Date 30-Nov-23; A0F0016A, Exp. Date 31-Dec-23; A0F0260A, A0F0261A, A0F0262A, Exp. Date 29-Feb-24; A0F0414A, A0F0415A, A0F0416A, A0F0417A, A0F0418A, Exp. Date 30-Apr-24; A0F0503A, Exp. Date 31-May-24, A0F0533A, A0F0534A, A0F0535A, A0F0536A, A0F0537A, A0F0540A, A0F0541A, Exp. Date 30-Jun-24; A0F0573A, A0F0574A, A0F0575A, A0F0592A, Exp. Date 31-Jul-24; A0F0596A, A0F0599A, Exp. Date 31-Aug-24 ; A0F0676A, 31-Oct-24.

Class II Drugs Event

Event ID:
93448

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
KINDER FARMS LLC
409 N Pacific Coast Hwy
Redondo Beach CA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
KinderMed KIDS' PAIN & FEVER Acetaminophen, 160 mg per 5 mL bottles, Oral Suspension, Organic Cherry Flavor, 4 FL OZ (118 mL), Distributed By: KinderFarms, Redondo Beach, CA 90277, NDC 82673-097-04, UPC 850001805728.

Product Quantity:
591,684 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0142-2024

Code Information:
Lot: CJ70900, CJ76796, Exp: 8/2024; CJ77051, Exp: 09/2024; WK02998, WK02997, WK04390, WK02999, Exp: 10/2024; WK03716, Exp:12/2024; WK05150, WK05151, WK07174, Exp:02/2025; WK05539, WK06534, Exp: 03/2025; WK10259, WK23040, Exp: 04/2025; WK27455, Exp: 08/2025.

Product Description:
KinderMed INFANTS' PAIN & FEVER Acetaminophen, 160 mg per 5 mL bottles, Oral Suspension, Organic Cherry Flavor, 2 FL OZ (59 mL), Distributed By: KinderFarms, Redondo Beach, CA 90277, NDC 82673-096-02, UPC 850001805698.

Product Quantity:
376,370 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0143-2024

Code Information:
Lot #: CJ70902, Exp: 07/2024; CJ76275, WJ81412, Exp: 08/2024; WK02194, WK02196, WK04141, WK02873, WK05542, Exp: 10/2024; WK02874, WK04794, Exp: 01/2025; WK04793, WK06535, Exp: 03/2025.

Class II Drugs Event

Event ID:
93496

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2023

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Wells Pharma of Houston LLC
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Philadelphia, Pennsylvania.

Associated Products

Product Description:
ceFAZolin sodium in Sterile Water for injection, Injectable Solution, 1g/10mL (0.1 g per mL), Syringe, Rx only, Wells Pharma, NDC 73702-131-10

Product Quantity:
825 syringes

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-0141-2024

Code Information:
Lot # 11092313110#01, Exp 01/12/24

Class II Drugs Event

Event ID:
93505

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2023

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
STAQ Pharma, Inc.
14135 E 42nd Ave Ste 50
Denver CO United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
ROPivacaine HCl 0.2% PF in Sodium Chloride 1,000 mg/500 mL (2 mg per mL) Injection, 500 mL bags, Rx only, STAQ Pharma Inc. 14135 E 42nd Ave, Unit 50, Denver, Colorado 80239, NDC 73177-0109-26,

Product Quantity:
2616 bags

Reason for Recall:
STAQ Pharma Inc. received consumer complaints related to leaking bags and other potential bag concerns. Upon investigation, they determine the source of the issue was with the bag manufacturer who released bags Lot # 134142-001A which had failed internal QC tests for leaks.

Recall Number:
D-0147-2024

Code Information:
Lot#: 23109472A, Exp. date 03/10/2024; 23109473A, Exp. date 03/11/2024; 23109474A, Exp. date 03/13/2024; 23109491A, Exp. date 03/16/2024; 23109492A, Exp. date 03/19/2024; 23109501A, Exp. date 03/25/2024; 23109520A, Exp. date 04/10/2024; 23109521A, Exp. date 04/13/2024; 23109522A, Exp. date 04/03/2024.

Class III Drugs Event

Event ID:
93316

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/06/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Right Value Drug Stores, LLC dba Carie Boyd's Prescription Shop
8400 Esters Blvd Ste 190
Irving TX United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
LET Gel (Lidocaine HCL/Epinephrine Bitartrate/Tetracaine HCL 4%/0.18%/0.5% Topical Gel), Single-use Topical Syringe, 3mL syringe, 10/pack, Rx only, Carie Boyd Pharmaceuticals, 8400 Esters Blvd, Ste# 190, Irving, TX 75063, NDC73271-1003-1

Product Quantity:
190 syringes

Reason for Recall:

Product Mix-up: Incorrect Product Formulation

Recall Number:
D-0140-2024

Code Information:
Lot#: 09202023@7, Exp 03/18/2024

Class III Drugs Event

Event ID:
93472

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/01/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
buPROPion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg, 60 Tablets bottle, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India NDC 47335-738-86

Product Quantity:
2016 Bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0137-2024

Code Information:
Lot HAD0630A, exp 1/2024