Enforcement Report - Week of May 22, 2024

Class I Drugs Event

Event ID:
94455

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/13/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Stop Clopez Corp
2301 Island Dr
Miramar, FL 33023-3546
United States

Distribution Pattern:
Distribution worldwide via amazon.com

Associated Products

Product Description:
Schwinnng Herbal Dietary Supplement Capsules, packaged in 10-count boxes, distributed by VSD Productions Inc., Las Vegas, NV.

Product Quantity:
5 boxes

Reason for Recall:
Marketed Without An Approved NDA/ANDA

Recall Number:
D-0494-2024

Code Information:
Lot 2108; EXP 10/31/2024

Class II Drugs Event

Event ID:
94355

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/12/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/13/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dercher Enterprises, Inc., DBA Gordon Laboratories
6801 Ludlow St
Upper Darby, PA 19082-2408
United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
Gordofilm Wart Remover (salicylic acid 16.7% USP) packaged in 15 cc glass jars, Gordon Laboratories, Upper Darby PA 19082, NDC 10481-3009-01

Product Quantity:
5,247 glass jars

Reason for Recall:
cGMP Deviations

Recall Number:
D-0495-2024

Code Information:
Lot #: F135, Exp. Date March 2025; F146, Exp. Date April , 2025; G103, Exp. Date January 2026; G194, Exp. Date September 2026

Class II Drugs Event

Event ID:
94486

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/15/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sagent Pharmaceuticals
1901 N Roselle Rd Ste 450
Schaumburg, IL 60195
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
MethylPREDNISolone Acetate Injectable Suspension, USP, 400 mg per 10 mL (40 mg per mL), 1 x 10 mL Multi-Dose Vial, Rx only, Mfd. for SAGENT Pharmaceuticals, Schaumburg, IL 60195, Made in India. NDC: 25021-820-10

Product Quantity:
14,360 vials

Reason for Recall:
Presence of Particulate Matter: Potential for black particulates in the drug product.

Recall Number:
D-0499-2024

Code Information:
Lots 5100186, 5100187, 5100188, 5100189, Exp 01/31/2025

Class II Drugs Event

Event ID:
94492

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
04/24/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/14/2024

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 (60 mL when reconstituted), 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046, India, NDC 68180-723-04

Product Quantity:
17,070 bottles

Reason for Recall:
Presence of foreign substance: Product complaint of foreign material in reconstituted bottle.

Recall Number:
D-0496-2024

Code Information:
Lot # F305442, Exp 8/30/2025

Product Description:
Cefdinir for Oral Suspension USP 125 mg/5 mL (60 mL when reconstituted), 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046, India, NDC 68180-722-04

Product Quantity:
17,040 bottles

Reason for Recall:
Presence of foreign substance: Product complaint of foreign material in reconstituted bottle.

Recall Number:
D-0497-2024

Code Information:
Lot # F305292, Exp 8/30/2025

Class II Drugs Event

Event ID:
94575

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/01/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/16/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharma Nobis LLC
7400 Alumax Rd
Texarkana, TX 75501-0282
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
CVS Health Magnesium Citrate Saline Laxative Oral Solution DYE FREE Cherry Flavor, 10 fl. oz bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, NDC 51316-881-10.

Product Quantity:
120830

Reason for Recall:
Microbial Contamination of Non-Sterile Products - Presence of Acetobacter nitrogenifigens bacteria

Recall Number:
D-0500-2024

Code Information:
Lot #: A81506, Exp 12/31/2025

Product Description:
Meijer Magnesium Citrate Saline Laxative Oral Solution Dye Free, Sugar Free Grape, 10 fl. oz bottle, Distributed by: Meijer Distribution Inc., Grand Rapids,MI 49544, NDC 79481-0034-9

Product Quantity:
24840

Reason for Recall:
Microbial Contamination of Non-Sterile Products - Presence of Acetobacter nitrogenifigens bacteria

Recall Number:
D-0501-2024

Code Information:
Lot #: A81834, Exp 1/31/2026

Class II Drugs Event

Event ID:
94592

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/15/2024

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
MACLEODS PHARMA USA, INC
103 College Rd E Fl 2
Princeton, NJ 08540-6611
United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP 50mg /12.5 mg, 1000-count bottle, Rx only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540, Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, INDIA, NDC 33342-050-44

Product Quantity:
1,048 bottles

Reason for Recall:
Presence of foreign substance: plastic-like substance.

Recall Number:
D-0498-2024

Code Information:
Lot #: BLK2304A, Exp. 07/31/2025