

Enforcement Report - Week of January 24, 2024

Class I Drugs Event

Event ID: 89106	Product Type: Drugs
Status: Ongoing	Date Terminated:
Recall Initiation Date: 11/23/2021	Voluntary / Mandated: Voluntary: Firm initiated
Center Classification Date: 01/17/2024	Initial Firm Notification of Consignee or Public: Press Release
Recalling Firm: The Procter & Gamble Company 1 Procter And Gamble Plz Cincinnati OH United States	

Distribution Pattern:
Nationwide USA and Puerto Rico, Canada, Guam, Northern Mariana Islands, American Samoa, Bhutan, Timor-Leste, Maldives, Fiji, US Virgin Islands, Trinidad, Peru, Saint Marteen, Bahamas, Costa Rica, Guatemala, Honduras, Panama, Belize, Santa Lucia, Aruba, Dominican Republic, Guyana

Associated Products

Product Description: Old Spice, PURE SPORT, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant & Deodorant Spray, Topical spray can, Net WT 6.0 OZ (170g), Distributed by Procter & Gamble, Cincinnati, OH 45202. NDC: 37000-199-60, UPC 0 12044 00191 2
Product Quantity: unknown
Reason for Recall: Chemical contamination: presence of benzene
Recall Number: D-0238-2024
Code Information: Lot #: 11661458SM, 11681458SB, Exp 5/31/23; 12621458SV, 12631458SB, Exp 08/31/23
Product Description: Old Spice, SWEAT DEFENSE PURE SPORT PLUS, Dry Spray, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g) cans, Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-387-10, UPC 0 37000 72974 7
Product Quantity: unknown
Reason for Recall: Chemical contamination: presence of benzene
Recall Number: D-0240-2024
Code Information: Lot #: 12081458SB, Exp 6/30/2021; 92181458FA, Exp 7/31/21;
Product Description: Old Spice, SWEAT DEFENSE ULTIMATE CAPTAIN, Aluminum Chlorohydrate 23.5%, Anti-Perspirant, Topical spray can 3.8 OZ (107 g), Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-385-10, UPC 0 37000 74947 9
Product Quantity: unknown

Reason for Recall:

Chemical contamination: presence of benzene

Recall Number:

D-0241-2024

Code Information:

Lot #: 03581458SA, Exp 11/30/2022; 10251458SU, 10261458SA, Exp 12/31/2022;

Product Description:

Secret, powder fresh, Aluminum chlorohydrate 24%, Anti-Perspirant/Deodorant, Topical spray can Net Wt., (a) 4OZ (113g), NDC 37000-134-11, UPC 0 37000 71109 4, (b) 6OZ (170g), NDC 37000-134-17, UPC 0 37000 71108 7; (c) twin pack-2 each can Net Wt. 6OZ (170g), NDC: 37000-134-01, UPC 0 37000 58690 6; Distr. by: Procter & Gamble, Cincinnati, OH 45202

Product Quantity:

unknown

Reason for Recall:

Chemical contamination: presence of benzene

Recall Number:

D-0242-2024

Code Information:

Lot #: (a &b) 00701458SJ, 00861458SA, 00871458SA, Exp 1/28/2022; 00921458SK, Exp 3/31/2022; 01701458SJ, 01711458SE, Exp 5/31/2022; 03431458SA, 03441458SA, 03531458SM, Exp 11/30/2022; 10681458SJ, 10691458SA, 10701458SA, 10781458SE, 10811458SJ, Exp 2/28/2023; 11701458SH, 11711458SH, 11721458SG, Exp 5/31/2023; 12181458SD, Exp 7/31/23; 12631458SH, 12641458SB, 12651458SE, Exp 8/31/23; 10301458SA, Exp 12/31/22; 10921458SJ, 10931458SA, 11191458SJ, Exp 3/31/23; 11251458SB, 11421458SM, 11431458SB, Exp 4/30/2023; 11701458SH, 11711458SB, Exp 5/31/2023; 12101458SJ, 12121458SJ, Exp 6/30/2023 (c) 11711458SB, Exp 5/31/2023

Product Description:

Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Waterlily, Topical Spray Can, Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-381-10; UPC 0 37000 72372 1; 12/pack UPC 0 37000 72991 4

Product Quantity:

unknown

Reason for Recall:

Chemical contamination: presence of benzene

Recall Number:

D-0243-2024

Code Information:

Lot #: 92191458FB, Exp 7/31/2021; 00091458SA, Exp 12/31/2021; 00091458SA, 11821458SB, Exp 6/30/2023.

Product Description:

Secret, Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Lavender, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-383-10, UPC: 0 37000 72986 0

Product Quantity:

unknown

Reason for Recall:

Chemical contamination: presence of benzene

Recall Number:

D-0244-2024

Code Information:

Lot #: 00221458SU, 00231458SA, Exp 12/31/2021; 10271458SR, Exp 12/31/2022.

Product Description:

Secret, Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Rose, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-380-10, UPC 0 37000 79884 2

Product Quantity:

unknown

Reason for Recall:

Chemical contamination: presence of benzene

Recall Number:

D-0246-2024

Code Information:

Lot #: 12001458SF, Exp 06/30/2023.

Class I Drugs Event

Event ID:

93681

Status:

Ongoing

Recall Initiation Date:

12/21/2023

Center Classification Date:

01/17/2024

Recalling Firm:

Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico.

Product Type:

Drugs

Date Terminated:

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

4.2% Sodium Bicarbonate Injection, USP 5 mEq/10 mL (0.5 mEq/mL), Glass ABBOJECT Unit of Use Syringe, For Intravenous Use, Rx Only, 10 mL Syringe per Carton, Hospira, Inc., Lake Forst, IL 60045, NDC 0409-5534-24 (carton), 0409-5534-14 (case).

Product Quantity:

34000 Cartons

Reason for Recall:

Presence of Particulate Matter; identified as glass

Recall Number:

D-0233-2024

Code Information:

Lot GX1542, Exp. 01/01/2025

Product Description:

8.4 % Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL), Lifeshield, Glass ABBOJECT Unit of Use Syringe, Rx Only, 50 mL Syringe per Carton, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-6637-24 (carton), 0409-6637-14 (case).

Product Quantity:

21200 Cartons

Reason for Recall:

Presence of Particulate Matter; identified as glass

Recall Number:

D-0234-2024

Code Information:

Lot HA7295, EXP 03/01/2025

Product Description:

Atropine Sulfate Injection, USP 1 mg/10 mL (0.1 mg/mL), Lifeshield, Glass ABBOJECT Unit of Use Syringe, Rx Only, 10 mL Syringe per Carton, Hospira, Inc., Lake FOrrest, IL 60045, NDC 0409-4911-11 (carton), 0409-4911-34 (case).

Product Quantity:

24400 Cartons

Reason for Recall:
Presence of Particulate Matter; identified as glass

Recall Number:
D-0235-2024

Code Information:
Lot GY2496, Exp 02/01/2025

Class I Drugs Event

Event ID:
93691

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company
660 White Plains Rd Ste 250
Tarrytown NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Americaine, (benzocaine 20%) Benzocaine Topical Anesthetic Spray, Aerosol Can 2 oz (57 G), Dist. by Insight Pharmaceuticals Corp. Tarrytown, NY 10591, USA, A Prestige Consumer Healthcare company. Made in India. NDC 63736-378-02, Can UPC 3 63736 37882 0; Case UPC 1 03 63736 37882 7

Product Quantity:
34,704 cans

Reason for Recall:
Chemical Contamination: presence of benzene

Recall Number:
D-0236-2024

Code Information:
Lot # 1A16420, exp. date 01/31/2025

Class II Drugs Event

Event ID:
89106

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/23/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/17/2024

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
The Procter & Gamble Company

1 Procter And Gamble Plz
Cincinnati OH United States

Distribution Pattern:

Nationwide USA and Puerto Rico, Canada, Guam, Northern Mariana Islands, American Samoa, Bhutan, Timor-Leste, Maldives, Fiji, US Virgin Islands, Trinidad, Peru, Saint Marteen, Bahamas, Costa Rica, Guatemala, Honduras, Panama, Belize, Santa Lucia, Aruba, Dominican Republic, Guyana

Associated Products

Product Description:

Old Spice, SWEAT DEFENSE, STRONGER SWAGGER, Dry Spray, 48 Hour, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical Spray Can, Net WT 3.8 oz (107 g), Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC 69423-386-10, UPC 0 37000 73034 7 OR UPC 0 12044 04475 9 (12 Pack, older label)

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0239-2024

Code Information:

All lots with expiry through September 2023,

Product Description:

Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Light Essentials, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-382-10, UPC 0 37000 72992 1

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0245-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret, OUTLAST, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Completely Clean, Topical spray can 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-384-10, UPC 0 37000 74764 2

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0247-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret OUTLAST Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Protecting Powder, Topical spray can 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-478-10, UPC 0 37000 74772 7

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0248-2024

Code Information:

All lots with expiry through September, 2023

Product Description:

Old Spice Pure Sport 2021 Gift Set, Contains: Old Spice Pure Sport Body Wash 18 Fl Oz (532 mL), 2-in-1 Shampoo & Conditioner 13.5 Fl Oz (400 mL), and Old Spice, SWEAT DEFENSE PURE SPORT PLUS, Dry Spray, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g). Dist. by: Procter & Gamble, Cincinnati, OH 45202. Gift Set NDC 69423-590-01, UPC 12044 04853 5

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0249-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Old Spice, PURE SPORT, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant & Deodorant Spray, Topical spray can, Net WT 6.0 OZ (170g), Distributed by Procter & Gamble, Cincinnati, OH 45202. NDC: 37000-199-60, UPC 0 12044 00191 2

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0250-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Old Spice, SWEAT DEFENSE PURE SPORT PLUS, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g) cans, Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-387-10, UPC 0 37000 72974 7

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0251-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Old Spice, SWEAT DEFENSE ULTIMATE CAPTAIN, Aluminum Chlorohydrate 23.5%, Anti-Perspirant, Topical spray can 3.8 OZ (107 g), Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-385-10, UPC 0 37000 74947 9

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0252-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret, powder fresh, (Aluminum chlorohydrate 24%), Anti-Perspirant/Deodorant, Topical spray can Net Wt., (a) 4OZ (113g), NDC 37000-134-11,

UPC 0 37000 71109 4, (b) 6OZ (170g), NDC 37000-134-17, UPC 0 37000 71108 7; (c) twin pack-2 Topical spray cans, each can Net Wt. 6OZ (170g), NDC: 37000-134-01, UPC 0 37000 58690 6; Dist. by: Procter & Gamble, Cincinnati, OH 45202,

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0253-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret, Dry Spray, Aluminum chlorohydrate 23.5% Antiperspirant, Waterlily, Topical Spray Can, Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-381-10; UPC 0 37000 72372 1; 12/pack UPC 0 37000 72991 4

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0254-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Lavender, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-383-10, UPC: 0 37000 72986 0

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0255-2024

Code Information:

All lots with expiry through September 2023

Product Description:

Secret Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Rose, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-380-10, UPC 0 37000 79884 2

Product Quantity:

unknown

Reason for Recall:

CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene

Recall Number:

D-0256-2024

Code Information:

All lots with expiry through September 2023

Class II Drugs Event

Event ID:

93682

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

12/21/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/12/2024

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Pharma Nobis LLC

7400 Alumax Rd

Texarkana TX United States

Distribution Pattern:

Nationwide.

Associated Products

Product Description:

Good Neighbor Pharmacy, DYE FREE, SUGAR FREE Magnesium Citrate Saline Laxative, Oral Solution, Cherry Flavor 10 fl. oz, Distributed by AmerisourceBergen, 1 West First Ave, Conshohocken, PA 19428, NDC 46122-741-38

Product Quantity:

24,684 Bottles

Reason for Recall:

MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

Recall Number:

D-0227-2024

Code Information:

Lots A80673, A80742; Exp 10/31/2025

Product Description:

Walgreens Dye-Free Magnesium Citrate Saline Laxative/Oral Solution, Sugar Free Low Sodium, Grape flavor 10 fl. oz, Distributed by: Walgreen Co, 200 Wilnot Rd, Deerfield, IL 60015, NDC 0363-0427-98.

Product Quantity:

49,716 Bottles

Reason for Recall:

MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

Recall Number:

D-0228-2024

Code Information:

Lot A80623; Exp. 11/30/2025

Product Description:

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

Product Quantity:

13,344 bottles

Reason for Recall:

MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

Recall Number:

D-0229-2024

Code Information:

Lot A80763; Exp. 11/2025

Product Description:

Freskaro refresh & revitalize Magnesium Citrate Saline Laxative Oral Solution Grape Flavor 10 fl. oz, Manufactured by: Pharma Lobis, 7400 Alumax Dr., Texarkana, TX 75501, NDC 82645-311-10.

Product Quantity:

53,268 Bottles

Reason for Recall:

MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

Recall Number:

D-0230-2024

Code Information:

Lot A80553; Exp. 11/2025

Product Description:

Freskaro refresh & revitalize Magnesium Citrate Saline Laxative Oral Solution Cherry Flavor 10 fl. oz, Manufactured by: Pharma Lobis, 7400 Alumax Dr., Texarkana, TX 75501, NDC 82645-312-10.

Product Quantity:

7,404 Bottles

Reason for Recall:

MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

Recall Number:

D-0231-2024

Code Information:

Lot A80622; Exp. 11/2025

Class II Drugs Event

Event ID:

93701

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/29/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/17/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Ibuprofen and Famotidine Tablets 800mg/26.6mg, Rx Only, 90 Tablets per Bottle, manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC., Parsippany, NJ 07054, NDC 67877-626-90

Product Quantity:

3,288 bottles

Reason for Recall:

Presence of Foreign Tablet/Capsule: A stray Rasagiline Mesylate 1 mg tablet was discovered in an unopened bottle of Ibuprofen and Famotidine.

Recall Number:

D-0237-2024

Code Information:

23140190, Exp. Date 12/31/2024

Class II Drugs Event

Event ID:**Product Type:**

93805

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/11/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/16/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Par Sterile Products LLC
870 Parkdale Rd
Rochester MI United States

Distribution Pattern:

Nationwide USA

Associated Products

Product Description:

Vasopressin (vasopressin in 5% Dextrose) Injection, 20 units per 100 mL (0.2 units per mL), 100 mL x 10 Single Dose Vials per carton, Ready to Use, For Intravenous Infusion, Rx Only, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977. NDC: 42023-237-10

Product Quantity:

1721 cartons

Reason for Recall:

Superpotent Drug: Assay from the 3-month and 6-month stability intervals exceeded the upper specification limit.

Recall Number:

D-0232-2024

Code Information:

Lot # 66702; Exp. 02/2025