Enforcement Report - Week of November 8, 2023

Class II Drugs Event

Event ID:
93189

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/31/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Gynazole-1, (Butoconazole Nitrate) Vaginal Cream USP, 2%, Net Wt 5.8 g per pre-filled applicator, packaged in 1 prefilled applicator per carton, Rx Only, Manufactured By Padagis, Yeruham, Israel; Distributed By: Padagis, Allegan, MI 49010. NDC: 45802-396-01

Product Quantity:
10,512 cartons

Reason for Recall:
Incorrect Product Formulation: Hydrophilic Colloidal Silica was used to manufacture the product rather than Hydrophobic Colloidal Silica as required by the manufacturing process.

Recall Number:
D-0081-2024

Code Information:
Lot#: 164185, Exp. Date 4/2024

Class II Drugs Event

Event ID:
93220

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/19/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Safecor Health, LLC
317 New Boston St
Woburn MA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Strong Iodine Solution U.S.P. (Lugol's Solution) (Iodine 5%), 14 mL Glass Dropper bottle in box, RX only, Safecor Health, LLC, Woburn, MA 01801. NDC# 48433-230-15

Product Quantity:
166,022 bottles

Reason for Recall:
CGMP Deviations: Recall due to the absence of USP CGMP compendial requirements.

Recall Number:
D-0082-2024

Code Information:
Lot # 21A0073, Exp 11/30/2023; 21A0091, Exp. 12/31/2023; 21A0103, Exp 01/31/2024; 21A0135, Exp 03/31/2024; 22A0011, Exp 06/30/2024; 22A0019, Exp 07/31/2024; 22A0057, Exp 09/30/2024; 22A0083, Exp 11/30/2024; 22A0104, Exp 12/31/2024; 22A0110, Exp 01/31/2025; 22A0150, Exp 03/31/2025; 23A0007, Exp 06/30/2025; 23A0041, Exp 09/30/2025; 23A0045, Exp 11/30/2025; 23A0058, Exp 11/30/2025; 23A0067, Exp 11/30/2025; 23A0080, Exp 12/31/2025; 23A0090, Exp 01/31/2026

Class II Drugs Event

Event ID:
93255

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
12/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/27/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GlaxoSmithKline Consumer Healthcare Holdings LLC
320 S Broadway
Saint Louis MO United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Peppermint flavor, chewable tablets, 72-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0228-06, UPC 3-0766-0745-85-3

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0073-2024

Code Information:
Lot#: HB2G, Exp. Date 8/31/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Peppermint flavor, chewable tablets, packaged in 12-count roll, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0228-01, UPC 3-0766-0746-80-5

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0074-2024

Code Information:
Lot #: HA7G, Exp. Date 8/31/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Fruit flavor, Chewable Tablets, packaged in 160-count bottles, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0118-14, UPC 3-0766-0746-10-2

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0075-2024

Code Information:
Lot #: HV6B, Exp. Date 9/30/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 72-count bottles, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-02, UPC 3-0766-0746-50-8

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0076-2024

Code Information:
Lot #: HR5W, Exp. Date 09/30/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 12-count roll, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-03, UPC 3-0766-0746-70-6

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0077-2024

Code Information:
Lot#: HR6A, Exp. Date 09/30/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 265-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-05, UPC 3-0766-3072-14-7

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0078-2024

Code Information:
Lot #: J96X,J96W, Exp. Date 09/30/2027

Product Description:
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, chewable tablets, 72-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0118-83, UPC 3-0766-0746-50-8

Product Quantity:

Reason for Recall:
Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.

Recall Number:
D-0079-2024

Code Information:
Lot#: KH5L, Exp. Date 09/30/2027

Class II Drugs Event

Event ID:
93256

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2023

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Liothyronine Sodium Tablets, USP, 5 mcg, 100-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc.Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191,(U.T. of D & NH), India. NDC 62756-589-88

Product Quantity:
7392 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0083-2024

Code Information:
Lot #: DND0058A, Exp. Date 12/2023

Product Description:
Liothyronine Sodium Tablets, USP, 25 mcg, 100-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc.Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191,(U.T. of D & NH), India. NDC 62756-590-88

Product Quantity:
2304 Bottles

Reason for Recall:
Failed Impurities/Degradation Specifications.

Recall Number:
D-0084-2024

Code Information:
Lot #: DNC2204A, Exp. Date 11/2023

Class III Drugs Event

Event ID:
93236

Product Type:
Drugs

Status:

Date Terminated:

Ongoing

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/30/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Edenbridge Pharmaceuticals, LLC
1 Upper Pond Rd Ste 250
Parsippany NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Opium Tincture, USP (Deodorized), 10 mg/mL of anhydrous morphine, packaged in 118 mL (4 Fl oz) bottles, Rx only, Manufactured for: Edenbridge Pharmaceuticals, LLC Parsippany, NJ 07054, NDC 42799-217-01

Product Quantity:
4548 bottles

Reason for Recall:
Subpotent Drug

Recall Number:
D-0080-2024

Code Information:
Lot#: 23ZCP1, Exp. Date 02/22/2026;Lot #:23ZDR1, Exp. Date 03/09/2026

Class III Drugs Event

Event ID:
93252

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/02/2023

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:
Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP, 5mg/6.25mg, 100-count Bottle, RX only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC 68462-879-01

Product Quantity:
480 100-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0085-2024

Code Information:
Lot# 17212352, Exp 11/31/2023