

Enforcement Report - Week of January 21, 2026

Class II Drugs Event

Event ID:

97821

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

10/03/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/14/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Advanced Pharmaceutical Technology, Inc.

132 S Central Ave

Elmsford, NY 10523-3509

United States

Distribution Pattern:

GA, NY, TX, Puerto Rico, United Kingdom, Malta, Greece

Associated Products

Product Description:

TESTO-100 CIII (testosterone 100 mg), 10 Sterile Pellets per carton, Rx only, Manufactured by: Advanced Pharmaceutical Technology, 132 South Central Avenue, Elmsford, NY 10523, NDC# 57377-100-01

Product Quantity:

22,843 pellets

Reason for Recall:

Lack of Assurance of Sterility: Potential microbial contamination of subcutaneous pellets.

Recall Number:

D-0258-2026

Code Information:

Lot #: P-22-3, Exp 06-2027

Class II Drugs Event

Event ID:

98225

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/31/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/14/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Alvogen, Inc

44 Whippany Rd Ste 300

Morristown, NJ 07960-4558

United States

Distribution Pattern:

US Nationwide.

Associated Products

Product Description:

Levothyroxine Sodium Tablets, USP, Thyro-Tab, 150mcg, 1000 Tablets, Rx only, Manufactured by: LLOYD, Inc., Shenandoah, IA, 51601 USA, Distributed by: Alvogen, Inc., Pine Brook, NJ 07058 USA, NDC: 47781-662-10.

Product Quantity:

N/A

Reason for Recall:

Product Mix-Up: A single bottle of this lot was reported by a pharmacy to contain 88 mcg tablets instead of 150 mcg tablets.

Recall Number:

D-0259-2026

Code Information:

Lot # MHA21825, Exp Date: December 31, 2027

Class II Drugs Event

Event ID:

98239

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

12/26/2025

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/14/2026

Initial Firm Notification of Consignee or Public:

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:

GOLD STAR DISTRIBUTION INC
1000 Humboldt Ave N
Minneapolis, MN 55411-3964
United States

Distribution Pattern:

US Nationwide.

Associated Products

Product Description:

Advil a) Ibuprofen, Dispenser Pack, 2 tablet packets in box containing 50 individual packets, UPC: 305730154895; b) PM, Ibuprofen, Dispenser Pack, 2 Caplet packets in box containing 50 packets, UPC: 305730164559

Product Quantity:

Unkown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0261-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Aleve 1's, 60 CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0262-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Alka Seltzer, a) Original, 2 tablets per packet in 58 count box, UPC: 815556020033, 016500514473, b) Plus Cold & Flu, 2 tablets per packet in 36 count box, UPC: 016500594932

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0263-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Benadryl, 25'S 2PK Box, UPC 815556020316

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0264-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Bayer 2Pk- 25 CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0265-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Claritin, 20 Count, UPC: 655708016305

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0266-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

DAYQUIL COLD & FLU, 32CT/2PK

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0267-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

LIQUID DAYQUIL 12/8oz

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0268-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

EXCEDRIN 2'S DISP.- 30 CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0269-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

EXCEDRIN MIGRAINE 2'S- 25 CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0270-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

MOTRIN 2'S DISP.- 50CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0271-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

LIQUID NYQUIL a) regular, 12/8oz; b) cherry, 12/8oz

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0272-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

NYQUIL COLD & FLU -32CT/2PK

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0273-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

CHILDREN NYQUIL, COLD&FLU, BERRY, 8oz, 12ct

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0274-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

PEPTO BISMOL 32CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0275-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

PEPCID COMPLETE - 25CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0276-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

TYLENOL a) 500 MG., 2'S DISPLAY, 50CT; b) COLD & FLU, 25CT/2S; c) COLD & FLU SEVERE, 2PK, 50CT; d) PM, 50CT; e) SINUS SEVERE, 2PK, 50CT

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0277-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Halls Cough Drops a) BAGS, MENTHOL, 12CT; b) BAGS, HONEY LEM, 12CT; c) BAGS, DEFENSE CITRUS, 12CT; d) BAGS, CHERRY, 12CT; e) M. CHERRY, 20 STK; f) BRAZIL, Cherry, 21CT/27.5G; f) LEMON. HONEY, 20CT #1180E; g) LIME FRESH, 20CT, #1182; h) MENTHOL BLUE, 20CT, #1180A; i) BRAZIL, Menthol, 21CT/27.5G, j) M. STRAWBERRY, 20 STK; k) DEFENSE, VITAMIN C, 20CT, #1181

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0278-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

TUMS a) Assorted, 12 Ct.; b) Extra Strength (EX) Assorted Berries, 12-count #1194A *05/27; c)Extra Strength (EX) Assorted Fruit, 12-count, #1194C *03/27

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0279-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Swan, White Clear Alcohol, 50%, 16oz, 12 count

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0280-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Personal Care, Ice Gel, 8oz, 12 count, UPC 048155903463

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0281-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Carmex a) jar, 12 count, UPC: 083078123154, 083078113155; b) Tube, PEG, 12 count, UPC: 083078123147, 083078113148

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0282-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Personal Care, Vaporizing Chest Rub, 4 oz, 12 count, UPC 048155903319

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0283-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

LUCKY ICE, Cool Mouthwash, Alcohol Free, 16.9oz, 12CT, UPC: 808829108989

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0284-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Petroleum jelly: a) Vaseline Petroleum Jelly, 1.75, 12CT, UPC: 6001085120946; b) Vaseline Men Cooling Petroleum Jelly, 100ML, 12CT, UPC: 60022141; c) Vaseline Vitamin E, Petroleum Jelly, 100ML, 12CT, UPC: 6001085121028; MEN FRESH PETROLEUM JELLY, 100ML, 12CT, UPC: 60022127; d) Lucky Petroleum Jelly, 6 OZ, 12 PK, UPC: 808829081466;048155903562; e) Lucky Petroleum Jelly, COCOA, 6oz, 12ct, UPC: 808829081572, 048155922150; f) Personal Care, CREAMY PETROLEUM JELLY, 4.5oz, 12CT, UPC: 048155908642; g) Personal Care, CREAMY COCOA PETROLEUM JELLY, 4.5oz, 12CT, UPC: 048155922242; h) SOFTEE, PETROLEUM JELLY, 5oz, 12CT, UPC: 096002007208

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0285-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Deodorant: a) Axe, Body Spray, Wild Spice, 6CT, 150ML, UPC: 600108736469; b) LUCKY MENS STICK DEODORANT, SPRING FRESH, 24CT, 2.5 OZ, UPC: 808829111668; c) LUCKY MENS STICK DEODORANT, FRESH COMFORT, 24CT, 1.6 OZ, UPC: 808829089103; d) LADY DEODORANT, CHERRY BLOSSOM, 24CT, 1.8oz, UPC: 048155921092; e) AXE, BODY SPRAY, APOLLO, 6CT, 150ML; f) AXE, BODY SPRAY, BLACK, 6CT, 150ML; g) AXE, BODY SPRAY, DARK TEMPTATION, 6CT, 150ML; h) AXE, BODY SPRAY, GOLD, 6CT, 150ML; i) AXE, BODY SPRAY, EXCITE, 6CT, 150ML; j) AXE, BODY SPRAY, ICE CHILL, 6CT, 150ML; k) AXE, BODY SPRAY, MUSK, 6CT, 150ML; l) AXE, DEODORANT SPRAY, ADRENALIN, 6CT, 150ML

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0286-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Product Description:

Toothpaste: a) COLGATE, TOOTHPASTE, WHITENING, 2.5oz, 24ct; UPC: 035000511065; b) COLGATE, TOOTHPASTE, Regular, 2.5oz, 24ct, UPC: 035000511058; c) COLGATE, TOOTHPASTE, TRIPLE, 2.5oz, 24ct, UPC: 035000512109; d) COLGATE, TOOTHPASTE, MINT ZING, 24CT, 2.5oz, UPC: 035000744609; COLGATE, MAXFRESH, SPICY FRESH, RED TOOTH PASTE, 72CT, 150G; e) CREST, TOOTHPASTE, 40CT, 8.2OZ, UPC: 037000247081

Product Quantity:

N/A

Reason for Recall:

CGMP Deviations: Insanitary conditions including rodent exposure/activity in their distribution center.

Recall Number:

D-0287-2026

Code Information:

All lots within expiry distributed by Gold Star Distribution.

Class II Drugs Event

Event ID:

98247

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

01/02/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/15/2026

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

Cipla USA, Inc.

10 Independence Blvd

Warren, NJ 07059-2730

United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Lanreotide Injection, 120 mg/0.5 mL, 0.5 mL per pre-filled syringe, For deep subcutaneous injection, Rx Only, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-870-67

Product Quantity:

15,221 syringes

Reason for Recall:

Presence of Particulate Matter.

Recall Number:

D-0290-2026

Code Information:

Lot, expiry: 4301954IR1 , exp 31/10/2026 ; 4301994IR1 , exp 31/10/2026 ; 4301995IR1 , exp 31/10/2026 ; 4301996IR1 , exp 31/10/2026 ; 4400005IR1 , exp 30/11/2026 ; 4400006IR1 , exp 30/11/2026 ; 4400007IR1 , exp 30/11/2026 ; 4400124IR1 , exp 30/11/2026 ; 4400154IR1 , exp 30/11/2026 ; 4400155IR1 , exp 30/11/2026 ; 4400156IR1 , exp 30/11/2026 ; 4400373IR1 , exp 31/12/2026 ; 4400374IR1 , exp 31/12/2026 ; 4400375IR1 , exp 31/12/2026 ; 4400455IR1 , exp 31/1/2027 ; 4400456IR1 , exp 31/1/2027 ; 4400457IR1 , exp 31/1/2027 ; 4400544IR1 , exp 28/2/2027 ; 4400606IR1 , exp 28/2/2027 ; 4400607IR1 , exp 28/2/2027 ; 4400696IR1 , exp 28/2/2027 ; 4400697IR1 , exp 28/2/2027 ; 4400779IR1 , exp 28/2/2027 ; 4400780IR1 , exp 28/2/2027 ; 4400781IR1 , exp 28/2/2027 ; 4400844IR1 , exp 31/3/2027 ; 4400845IR1 , exp 31/3/2027 ; 4400849IR1 , exp 31/3/2027 ; 4400984IR1 , exp 31/3/2027 ; 4400985RIR , exp 31/3/2027 ; 4400986IR1 , exp 31/3/2027 ; 4401023IR1 , exp 31/3/2027 ;

Class II Drugs Event

Event ID:

98262

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

01/06/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/14/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Encon Safety Products Co
6825 W Sam Houston Pkwy N
Houston, TX 77041-4026
United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

AQ 120 GFEW, Aquarion Preserved Cartridges (2) 3.7 Gallons each

Product Quantity:

7677 bags

Reason for Recall:

cGMP deviations.

Recall Number:

D-0260-2026

Code Information:

Lot #: 239066, Exp. Date 1/24/2027; 378106, Exp. Date 3/8/2026; 379202, Exp. Date 3/29/2026; 379750, Exp. Date 4/24/2026; 380983, Exp. Date 5/24/2026; 382901, Exp. Date 7/11/2026; 384682, Exp. Date 8/16/2026; 386189, Exp. Date 9/20/2026; 387559, Exp. Date 10/11/2026; 388381, Exp. Date 11/2/2026; 398066, Exp. Date 1/24/2027; 389477, Exp. Date 2/21/2027; 392491, Exp. Date 3/13/2027; 393724, Exp. Date 4/3/2027; 394683, Exp. Date 4/29/2027; 395094, Exp. Date 5/29/2027; 395231, Exp. Date 6/18/2027; 395368, Exp. Date 7/17/2027; 397971, Exp. Date 11/8/2027; 398930, Exp. Date 8/28/2027; 399204, Exp. Date 9/25/2027; 400300, Exp. Date 10/16/2027; 403177, Exp. Date 11/8/2027; 403314, Exp. Date 11/25/2027; 405095, Exp. Date 1/24/2028; 406328, Exp. Date 2/14/2028; 407700, Exp. Date 4/3/2028; 407974, Exp. Date 4/17/2028; ; 410166, Exp. Date 6/13/2028; 410988, Exp. Date 7/1/2028.

Class III Drugs Event

Event ID:
98062

Status:
Ongoing

Recall Initiation Date:
11/26/2025

Center Classification Date:
01/14/2026

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
Nationwide in the USA.

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description: Clindamycin Phosphate USP, 1% (10 mg/mL), Topical Solution, 60 mL per applicator bottle, Rx only, Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel; Dist. by: Taro Pharmaceuticals USA, Inc., Hawthorne, NY 10532, NDC# 51672-4081-4
Product Quantity: N/A
Reason for Recall: Failed Impurities/Degradation: Out of Specification results for Total Impurities and for Assay.
Recall Number: D-0257-2026
Code Information: Lot#: AD30154, AD31143, AD31145, Exp 11/30/2025

Class III Drugs Event

Event ID:
98241

Status:
Ongoing

Recall Initiation Date:
12/30/2025

Center Classification Date:
01/13/2026

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton, NJ 08540-6620
United States

Distribution Pattern:
Nationwide within the USA

Product Type:
Drugs

Date Terminated:
N/A

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description: Fluocinolone Acetonide Solution Topical Solution USP, 0.01%, 60-mL bottles, Rx only, Dist. by: Taro Pharmaceuticals Inc., Hawthorn, NY 10532. NDC 51672-1365-4

Product Quantity:

24,624 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications: Out of specification result was obtained for the known impurity D.

Recall Number:

D-0256-2026

Code Information:

Lot #: AD81290, AD81291, AD81292 and AD81293, Exp. Date 1/31/2027