Enforcement Report - Week of March 19, 2025

Class I Drugs Event

Event ID:
96250

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/10/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ICU Medical, Inc.
600 N Field Dr
Lake Forest, IL 60045-4835
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
POTASSIUM CHLORIDE Inj., 20 mEq total in 100 mL flexible container 24 x case, 200 mEq/L, Rx Only, ICU Medical, Inc., Lake Forest, Illinois, 60045, USA, NDC# 0990-7075-26; Bar Code Flexible container (01) 00309907075266; Case (01)30309907075267

Product Quantity:
67,488 flexible containers

Reason for Recall:
Labeling: Label Error on Declared Strength. Cases labeled POTASSIUM CHLORIDE 20 mEq, may contain flexible containers with overwrap mislabeled as 10 mEq. The correct dosage strength of 20 mEq is printed on the labeling affixed to the product flexible container.

Recall Number:
D-0267-2025

Code Information:
Lot 1023172, Exp Date: 31 January 2026

Product Description:
POTASSIUM CHLORIDE Inj., 10 mEq total in 100 mL, 100 mEq/L flexible container, Rx Only, ICU Medical, Inc., Lake Forest, Illinois, 60045, USA, NDC# 0990-7074-26; Bar Code (01)00309907074269

Product Quantity:
unknown

Reason for Recall:
Labeling: Label Error on Declared Strength. Overwrap labeled as Potassium Chloride Inj 10 mEq may contain flexible containers of Potassium Chloride Inj 20 mEq

Recall Number:
D-0268-2025

Code Information:
Lot 1023172, Exp Date: 31 January 2026

Class I Drugs Event

Event ID:
96262

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/14/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2025

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

Recalling Firm:
CareFusion 213, LLC
1550 Northwestern Dr
El Paso, TX 79912-8000
United States

Distribution Pattern:
Nationwide and Canada

Associated Products

Product Description:
BD ChloraPrep Clear 1mL Applicators, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Patient Preoperative Skin Preparation, Sterile Solution, 0.03 fl. oz (1 mL) each, 60 Applicators per Carton, CareFusion 213, LLC, El Paso, TX 79912, Subsidiary of Becton, Dickinson and Co., REF 930480, NDC 54365-400-31.

Product Quantity:
205,440 applicators

Reason for Recall:
Non-Sterility: contamination of Aspergillus penicillioides, due to breach in package lidding.

Recall Number:
D-0259-2025

Code Information:
Lot #: 3200240, Exp 6/30/2026

Class I Drugs Event

Event ID:
96307

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/20/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/11/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Central Admixture Pharmacy Services, Inc.
6580 Snowdrift Rd Ste 100
Allentown, PA 18106-9331
United States

Distribution Pattern:
Product was distributed nationwide within the United States

Associated Products

Product Description:
PHENYLephrine added to 0.9% sodium chloride, 40 mg/250 mL* (160 mcg/mL), Rx Only, CAPS, Central Admixture Pharmacy Services, Inc., 6580 Snowdrift Rd., Ste 100, Allentown, PA 18106, 855-275-2270, NDC 71285-6092-1.

Product Quantity:

1546 bags

Reason for Recall:
Presence of Particulate Matter

Recall Number:
D-0272-2025

Code Information:
Lot 37-928390, Exp Date, 03MAR2025; Lot 37-928796, Exp Date, 09MAR2025; Lot 37-928839, Exp Date, 10MAR2025

Class II Drugs Event

Event ID:
96209

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/09/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aspen Biopharma Labs Pvt., Ltd.
Plot No 10, Biotech Park Phase-II Lalgadi Malakpet Village,Turkapally, Shameerpet Mandal
Medchal Malkajgiri
India

Distribution Pattern:
Product was distributed to 3 distributors (1 Hong Kong and 2 accounts in Florida)

Associated Products

Product Description:
Bimatoprost NDC# 82187-1001-1 Container description: The product packed in double self-seal cover and finally packed in Aluminum cover for shipping.

Product Quantity:
400.0 gm

Reason for Recall:
CGMP violations

Recall Number:
D-0260-2025

Code Information:
Lot Numbers: HABTC0020123, exp. date Dec-2026 HABTC0050623, exp. date May-2027 HABTC0091023, exp. date Sep-2028

Product Description:
Alprostadil Container Description: Amber color bottle

Product Quantity:
3.0 gm

Reason for Recall:
CGMP violations

Recall Number:
D-0261-2025

Code Information:
Lot Numbers: HAALC0020922 exp. date AUG-2025

Product Description:
Finasteride NDC# 82187-1003-1 Container Description: The product packed in white poly bag containing black poly bag and tied each individual

finally packed in HDPE container for shipping.

Product Quantity:
120.0 kg

Reason for Recall:
CGMP violations

Recall Number:
D-0262-2025

Code Information:
Lot Numbers: HAFSC0040923, exp. date Aug-2027 HAFSC0050923, exp. date Aug-2027

Product Description:
Chlorambucil Container Description: The product packed in double self-seal cover and finally packed in Aluminum cover for shipping.

Product Quantity:
5.1 kg

Reason for Recall:
CGMP violations

Recall Number:
D-0263-2025

Code Information:
Lot Numbers: HACUC0010722, exp. date Jun-2025 HACUC0010123, exp. date Dec-2025

Product Description:
Latanoprost NDC# 82187-1002-1 Container Description: Amber colour bottle

Product Quantity:
150.0 gm

Reason for Recall:
CGMP violations

Recall Number:
D-0264-2025

Code Information:
Lot Numbers: HALAC0010123, exp. date Dec-2026 HALAC0050923, exp. date Aug-2027

Product Description:
Voriconazole Container Description: voriconazole The product packed in white poly bag containing black poly bag and tied each individual finally packed in HDPE container for shipping.

Product Quantity:
4.0 kg

Reason for Recall:
CGMP violations

Recall Number:
D-0265-2025

Code Information:
Lot Number: HAVZC0020922, exp. date AUG-2026

Class II Drugs Event

Event ID:
96324

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/13/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/12/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Johnson, S C and Son, Inc
1525 Howe St
Racine, WI 53403-2237
United States

Distribution Pattern:
Nationwide within the United States and Canada

Associated Products

Product Description:
Kids by babyganics SPF 50 totally tropical (titanium dioxide 3/5%, zinc oxide 7.25%) packaged in a) 6 OZ (170 g) spray bottles UPC 813277019954 and UPC 813277019800; and b) Twinpack UPC 813277019930; Dist. by KAS Direct LLC, 1525 Howe St. Racine, WI 53403.

Product Quantity:
449,502 units

Reason for Recall:
Chemical Contamination

Recall Number:
D-0275-2025

Code Information:
a) UPC 813277019954 Lot #: A034 / 5810343A, A034 / 5820343A, Exp. Date Feb-25; A282 / 0122853A, A289 / 0132853A, Exp. Date Oct-25; C010 / 1680174A, C011 / 1690174A, Exp. Date Jan-26; C218 / 2592224A, C218 / 2602224A, Exp. Date Aug-26. UPC 813277019800 Lot #: A142 / 3901443A, A142 / 3911443A, A142 / 3921443A, Exp. Date May-25; A278 / 0142843A, A279 / 0152843A, A279 / 0162843A, Exp. Date Oct-25; A314 / 4473263A, A314 / 4483263A, A317 / 4493263A, Exp. Date Nov-25; C046 / 0100594A, C047 / 0110594A C050 / 0120594A, Exp. Date Feb-26; C068 / 2770774A, C071 / 2790774A, Exp. Date Mar-26; C102 / 9621154A, C102 / 9621154B, C102 / 9621154C, Exp. Date Apr-26; C144 / 4721534A, C144 / 4731534A, C144 / 4741534A, C144 / 4751534A, Exp. Date May-26 b) UPC 813277019930 Lot #: A033 / 5830343A, Exp. Date Feb-25; A079 / 9620893A, A079 / 9630893A, Exp. Date Mar-25; A142 / 3881453A, A142 / 3891453A, Exp. Date May-25

Product Description:
Kids by babyganics SPF 50 mineral sunscreen totally tropical (titanium dioxide 3/5%, zinc oxide 7.25%), packaged in 3 OZ spray bottles, Dist. by KAS Direct LLC, 1525 Howe St. Racine, WI 53403, UPC 813277019923 and UPC 813277019916

Product Quantity:
493,462 units

Reason for Recall:
Chemical Contamination

Recall Number:
D-0276-2025

Code Information:
UPC 813277019916 Lot #: A033 / 5880343A, A054 / 2030633A, A058 / 2050633A, A058 / 2050633B, A058 / 2060633A, A058 / 2070633A, A058 / 2040633A, A059 / 2080633A, Exp. Date Feb-25; A314 / 4513223A, Exp. Date Nov-25; C054 / 2090774A, C057 / 2100774A, Exp. Date Feb-26; C131 / 3201394A, C131 / 3211394A, C131 / 3211394B, C131 / 3211394C, Exp. Date May-26 UPC 813277019923 Lot #: A060 / 3780693A, A060 / 3780693B, Exp. Date Mar-25; C067 / 2110774A, C067 / 2110774B, C067 / 2110774C, Exp. Date Mar-26; C169 / 7921734A, C169 / 7921734B, Exp. Date Jun-26

Class II Drugs Event

Event ID:
96380

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/11/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc.
200 Connell Dr Ste 4200
Berkeley Heights, NJ 07922-2805
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules, USP, 60mg, Rx Only, 1000-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-748-10

Product Quantity:
11,100 bottles.

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit.

Recall Number:
D-0269-2025

Code Information:
Lot#: 240301C, Expiration: 01/2027.

Product Description:
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, 1000-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-747-10

Product Quantity:
14,749 bottles.

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit.

Recall Number:
D-0270-2025

Code Information:
Lot#: 240225C, Expiration: 01/2027

Product Description:
Duloxetine Delayed-Release Capsules, USP, 20mg, Rx Only, 500-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-746-05

Product Quantity:
11,125 bottles.

Reason for Recall:
CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit.

Recall Number:
D-0271-2025

Code Information:
Lot#: 240098C, Expiration: 01/2027.

Class II Drugs Event

Event ID:
96384

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denison Pharmaceuticals, LLC
1 Powder Hill Rd
Lincoln, RI 02865-4407
United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Zapzyt, Acne Treatment Gel, 10% benzoyl peroxide Gel, packaged in 1 oz (28.35g) tube, Distributed by: FOCUS CONSUMER HEALTHCARE, LLC., 801 Broad St Ste 200, Chattanooga, TN 37402. NDC 71687-0011-1

Product Quantity:
642,131 tubes

Reason for Recall:
Chemical Contamination: Presence of benzene.

Recall Number:
D-0273-2025

Code Information:
Lot #: 9762, Exp. Date 2/28/2025; 9763, 9764, 9765, Exp. Date 3/31/2025; 9869, 9870, Exp. Date 5/31/2025; 9871, 9872, Exp. Date 7/31/2025; 9996, 9997, 9998, Exp. Date 8/31/2025; 9995, Exp. Date 10/31/2025; 0154, 0153, 0326, Exp. Date 1/31/2026; 0155, 0156, 0161, 0327, 0329, 0328, Exp. Date 2/28/2026; 0479, 0480, Exp. Date 5/31/2026.

Class II Drugs Event

Event ID:
96391

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/04/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/10/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Chattem Inc
1715 W 38th St
Chattanooga, TN 37409-1248
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Unisom, SleepMelts, Diphenhydramine HCl tablets, 25 mg, Nighttime Sleep-Aid, 4 x 8 blister packs per carton, Cherry flavor, Manufactured by Adare Pharmaceuticals, Inc., Dist. by Chattem, Inc., P.O. Box 2219, Chattanooga, TN 37409, UPC # 0 41167 0014 0

Product Quantity:
180,696 cartons

Reason for Recall:
CGMP Deviations: Nitrosamine Drug Substance Related Issue impurity above the daily acceptable intake limit defined by the Food and Drug

Administration.

Recall Number:
D-0266-2025

Code Information:
Lot# 252807, Exp: 5/31/2025; 252808, Exp: 6/30/2025; 372560, Exp: 11/30/2025; 489576, 493447, Exp: 4/30/2026.

Class II Drugs Event

Event ID:
96395

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/12/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sigan Industries Group Inc.
296 Orenda Rd
Brampton
Canada

Distribution Pattern:
Nationwide in the U.S.A

Associated Products

Product Description:
Walgreens, Acne Control Cleanser, 10% Benzoyl Peroxide/Acne Treatment, NET WT 5 OZ (142g) Distributed by: Walgreen CO, 200 Wilmont RD, Deerfield, IL, Made in Canada. UPC#: 1 9560203602 8

Product Quantity:
13,440 tubes

Reason for Recall:
Chemical Contamination: Presence of benzene

Recall Number:
D-0274-2025

Code Information:
Lot#: 23-09328, Exp.: 09/2025

Class II Drugs Event

Event ID:
96419

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/10/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Nephron Sterile Compounding Center LLC
4500 12th Street Ext

West Columbia, SC 29172-3025
United States

Distribution Pattern:
US Nationwide.

Associated Products

Product Description:
Sodium Chloride Injection 9%, USP, 500 mL, Single-Dose IV Bottle, Rx Only, nephron, 503B outsourcing facility, West Columbia, SC 29172, NDC: 69374-334-50

Product Quantity:
4,190 bottles

Reason for Recall:
Lack of Assurance of Sterility: There is a potential for leakage at the IV bottle port.

Recall Number:
D-0257-2025

Code Information:
Lot # NA4008B, exp. date 03/03/2025 Lot # NA4005B & NA4005E, exp. date 02/20/2025

Class III Drugs Event

Event ID:
96379

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/24/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/07/2025

Initial Firm Notification of Consignee or Public:
N/A

Recalling Firm:
Kowa Pharmaceuticals America
530 Industrial Park Blvd
Montgomery, AL 36117-5543
United States

Distribution Pattern:
PA, OH, and TX

Associated Products

Product Description:
Livalo (pitavatstatin) tablets, 4 mg, 90-count bottles, Rx only, Manufactured by: Patheon, Inc. Cincinnati, OH 45237 USA or by Kowa Company, Ltd, Nagoya, 462-0024 Japan, Marketed by Kowa Pharmaceuticals: Kowa Pharmaceuticals America Inc., Montgomery, AL 36117 USA NDC 66869-404-90 HDPE Bottle, congregated into a shrink wrapped 6-pack further congregated into 24 6-packs in a cardboard case

Product Quantity:
5,328 Bottles

Reason for Recall:
Presence of foreign tablets/capsules

Recall Number:
D-0258-2025

Code Information:
Lot#: 3231300, Exp 8/2027