Enforcement Report - Week of April 2, 2025

Class I Drugs Event

Event ID:
96290

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ascent Consumer Products Inc.
105 Baylis Rd
Melville, NY 11747-3833
United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System (sodium bicarbonate USP 700 mg and sodium chloride USP 2300 mg), 30-count All Natural USP Grade Saline Packets and 1 Soft tip Squeeze Bottle, Net WT 0.1OZ (3g) each, Distributed by Ascent Consumer Products Inc., Melville, NY 11747, UPC 6 46011 00104 1

Product Quantity:
4,176 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Bacterial contamination with Staphylococcus aureus

Recall Number:
D-0299-2025

Code Information:
Lot# 024122661Al, Exp Date 12/2027

Product Description:
SinuCleanse Premixed SALINE PACKETS (sodium bicarbonate USP 700 mg and sodium chloride USP 2300 mg) for Nasal Wash System, 60-count All Natural USP Grade Saline Packets, Net WT 0.1OZ (3g) each, Distributed by Ascent Consumer Products Inc., Melville, NY 11747, UPC 6 46011 00103 4

Product Quantity:
unknown

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Bacterial contamination with Staphylococcus aureus

Recall Number:
D-0300-2025

Code Information:
Lot# 024122661Al, Exp Date 12/2027

Product Description:
SinuCleanse Soft Tip NETI POT Nasal Wash System (sodium bicarbonate USP 700 mg and sodium chloride USP 2300 mg), 30-count All Natural USP Grade Saline Packets and 1 kettle style Neti Pot, Net WT 0.1OZ (3g) each, Distributed by Ascent Consumer Products Inc., Melville, NY 11747, UPC 6 46011 00102 7

Product Quantity:

unknown

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Bacterial contamination with Staphylococcus aureus

Recall Number:
D-0301-2025

Code Information:
Lot# 024122661AI, Exp Date 12/2027

Class II Drugs Event

Event ID:
96313

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/25/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/21/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
A-S Medication Solutions LLC
2401 Commerce Dr
Libertyville, IL 60048-4464
United States

Distribution Pattern:
Nationwide in U.S.

Associated Products

Product Description:
METFORMIN HYDROCHLORIDE EXTENDED- RELEASE 500MG, 180 TABLETS, Packaged BY: A-S Medication Solutions, Libertyville, IL 60048 NDC 50090-1494-3.

Product Quantity:
411 180-count bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules.

Recall Number:
D-0292-2025

Code Information:
Lot# 4260340; Exp.12/31/2025.

Class II Drugs Event

Event ID:
96334

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/08/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2025

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Johnson, S C and Son, Inc

1525 Howe St
Racine, WI 53403-2237
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
babyganics, Sheer Blend, SPF 50 Mineral Sunscreen Fragrance Free (zinc oxide 20%), a) 1.7 FL OZ (50 mL) bottle, UPC 810035921658, b) 8 FL OZ (236 mL) bottle, UPC 810035921382, Dist. by KAS Direct, LLC, 1525 Howe St., Racine, WI 53403, Made in Canada.

Product Quantity:
57,184 bottles

Reason for Recall:
Failed stability specifications: during routine stability monitoring quality concerns were identified. Physical separation for ingredients was observed.

Recall Number:
D-0298-2025

Code Information:
Lot #: a) 097C4/C080316, Exp 03/31/2026; b) 177K3/A303407, Exp 10/31/2025

Class II Drugs Event

Event ID:
96412

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/05/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma, Inc.
1 Ram Ridge Rd
Chestnut Ridge, NY 10977-6714
United States

Distribution Pattern:
Nationwide in the U.S

Associated Products

Product Description:
Testosterone Gel 1%, 2.5 grams, 30 Unit-dose packets in a carton, Rx only, Distributed by: Strides Pharma Inc., East Brunswick, NJ, NDC 64380-151-02

Product Quantity:
195,952 Cartons; 30 sachets/Carton.

Reason for Recall:
Presence of foreign substance: Presence of Benzene.

Recall Number:
D-0293-2025

Code Information:
Lot #: 5501127A, 5501236A, Exp Apr-25; 5501341A, Exp Jun-25; 5501406A, Exp Jul-25; 5501408A, Exp Aug-25; 5501516A, Exp Sep-25; 5501568A, Exp Oct-25; 5501829A, Exp Mar-26; 5502000A, Exp Jul-26; 5502004A, 5502005A, Exp Aug-26; 5502092A, Exp Oct-26; 5502217A, Exp Dec-26; 5502262A, Exp Jan-27

Product Description:
Testosterone Gel 1%, 5 grams, 30 Unit-dose Packets in a carton, Rx only, Distributed by: Strides Pharma Inc., East Brunswick, NJ, NDC 64380-152-02

Product Quantity:
244,412 Cartons; 30 sachets /Carton

Reason for Recall:
Presence of foreign substance: Presence of Benzene.

Recall Number:
D-0294-2025

Code Information:
Lot #: 5501103A, Exp Mar-25; 5501237A, 5501238A, Exp Apr-25; 5501278A, Exp May-25; 5501280A, 5501342A, Exp Jun-25; 5501372A, Exp Jul-25; 5501496A, Exp Aug-25; 5501499A, Exp Sep-25; 5501580A, Exp Oct-25; 5501582A, Exp Dec-25; 5501653A, 5501656A, Exp Jan-26; 5501770A, Exp Feb-26; 5501842A, 5501868A, 5501882A, Exp Apr-26; 5501957A, Exp May-26; 5502001A, Exp Jul-26; 5502033A, Exp Aug-26; 5502112A, 5502115A, Exp Oct-26; 5502180A, 5502181A, Exp Nov-26.

Class II Drugs Event

Event ID:
96446

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/25/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
QuVa Pharma, Inc.
1075 W Park One Dr Ste 100
Sugar Land, TX 77478-2576
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
fentaNYL Citrate PF 200 mcg/100 mL (2 mcg/ml) /0.1% Bupivacaine HCl 100 mg/100 mL (1 mg/mL), 100 ml in NS Yellow CADD FSFF, Injection for Epidural Use (Not intended For IV Use), Compounded, For Institutional or Office Use Only, QuVa Pharma, 1075 West Park One Drive, Suite 100, Sugar Land, Tx 77478. NDC: 70092-1255-75

Product Quantity:
N/A

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0295-2025

Code Information:
Lots: 10140259, 10140539, 10140687, 10140688; Exp 04/24/2025

Product Description:
fentaNYL Citrate PF 200 mcg/100 mL (2 mcg/ml) /0.125% Bupivacaine HCl 125 mg/100 mL (1.25 mg/mL), 100 ml in NS Yellow CADD FSFF, Injection for Epidural Use (Not intended For IV Use), Compounded, For Institutional or Office Use Only, QuVa Pharma, 1075 West Park One Drive, Suite 100, Sugar Land, Tx 77478. NDC: 70092-1255-75

Product Quantity:
2,310 cassettes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0296-2025

Code Information:
Lot, expiry: Lots 10140284, 10140285, 10140315, 10140316, exp 04/08/2025; Lot 10140510, exp 04/14/2025; Lot 10140916, exp 04/24/2025

Product Description:
fentaNYL Citrate PF 200 mcg/100 mL (2 mcg/ml) /0.2% ROPivacaine HCl 200 mg/100 mL (2 mg/mL), 100 ml in NS Yellow CADD FSFF, Injection for Epidural Use (Not intended For IV Use), Compounded, For Institutional or Office Use Only, QuVa Pharma, 1075 West Park One Drive, Suite 100, Sugar Land, Tx 77478. NDC: 70092-1259-75

Product Quantity:
1,765 cassettes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0297-2025

Code Information:
Lot, expiry: Lot 10140303, exp 04/14/2025; Lots 10140867, 10140868, exp 04/24/2025; Lot 10140965, exp 04/28/2025

Class II Drugs Event

Event ID:
96475

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/27/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Consumer Product Partners, LLC
1 Swan Dr
Smyrna, TN 37167-2099
United States

Distribution Pattern:
VA

Associated Products

Product Description:
[CORRECT FRONT PANEL] Hydrogen Peroxide Topical Solution, USP, 32 FL OZ (1 QT) 946 mL per bottle, NDC 0869-0871-45; [INCORRECT BACK LABEL] Isopropyl alcohol 91%, Dist. by: Amazon.com Services, LLC, Seattle, WA 98109.

Product Quantity:
25,932 bottles

Reason for Recall:
Labeling; Label Mixup; some bottles have an incorrect back label indicating 91% Isopropyl Alcohol

Recall Number:
D-0302-2025

Code Information:
Lot 0643188, exp. date 10/22/2026

Class II Drugs Event

Event ID:
96481

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/27/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir, NC 28645-3618
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP, 50 mEq/50 mL (1 mEq/mL), 25 x 50 mL Single Dose Vials per carton, For Intravenous Use Only, Rx Only, Manufactured by: Exela Pharma Sciences, LLC, Lenoir, NC 28645. NDC Inner Vial: 51754-5001-1; NDC Carton: 51754-5001-4

Product Quantity:
103,950 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0303-2025

Code Information:
Lots: 10006417 and 10006418, Exp. 11/30/2026