

Enforcement Report - Week of September 21, 2022

Class I Drugs Event

Event ID:

90599

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

07/15/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/09/2022

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Vi-Jon, LLC

1 Swan Dr

Smyrna TN United States

Distribution Pattern:

Distributed Nationwide in the USA as well as Canada and Panama.

Associated Products

Product Description:

CVS Health, Magnesium Citrate SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), a) UPC 0 50428 30594 2; b) UPC 0 50428 33517 8; Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895.

Product Quantity:

241,086 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1500-2022

Code Information:

Lot# (a) 0556808, EXP 12/8/2023; 0563095, EXP 2/18/2024; 0562243, EXP 2/17/2024; 0557622, EXP 1/12/2024; (b) 0498395, EXP 8/8/2022

Product Description:

equate Magnesium Citrate, SALINE LAXATIVE, (1.745g/fl oz) 10 FL OZ (296mL), Grape Flavor, Distributed By: Walmart, Inc. Bentonville, AR 72716; NDC 49035-592-38 UPC 6 81131 28715 9

Product Quantity:

18,324 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1501-2022

Code Information:

Lot# 0525509, EXP 3/6/2023

Product Description:

EQUALINE magnesium citrate saline laxative, oral solution, (1.745 g/fl oz), DYE FREE lemon flavor, 10 FL OZ (296 mL), Distributed by Supervalu Inc. Eden Prairie, MN 55344 USA, or Distributed By UNFI Providence, RI 02908, NDC 41163-769-38 UPC 0 41163 50068 6

Product Quantity:

5,304 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1502-2022

Code Information:

Lot # 0511629, EXP 12/4/2022

Product Description:

Kroger, Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), Distributed By The Kroger CO Cincinnati, Ohio 45202; NDC 30142-899-38 UPC 0 41260 00182 6

Product Quantity:

44,976 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1503-2022

Code Information:

Lot# 0557622, EXP 1/12/2024

Product Description:

meijer, magnesium citrate Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544; NDC 41250-708-38 UPC 7 13733 45945 7

Product Quantity:

L 22,965,330 C 10,070,526 G 8,064,834

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1504-2022

Code Information:

Lot# 0557622, EXP 1/12/2024

Product Description:

P, magnesium citrate SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By Publix Super Markets, Inc. 3300 Publix Corporate Parkway, Lakeland, FL 33811; NDC 56062-266-38 UPC 0 41415 50673 2

Product Quantity:

8,682 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1505-2022

Code Information:

Lot # 0562243, EXP 2/17/2024

Product Description:

Rexall, Magnesium Citrate Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By Dolgencorp. LLC 100 Mission Ridge, Goodlettsville, TN 37072 or Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; NDC 55910-183-38, UPC 0 72785 13418 8

Product Quantity:

42,912 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1506-2022

Code Information:

Lot # 0511629, EXP 12/4/2022; 0562243, EXP 2/17/2024

Product Description:

SWAN, Citroma MAGNESIUM CITRATE, Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemony Flavor, 10 FL OZ (296 mL), Distributed by: Vi-Jon, Inc. One Swan Drive Smyrna, TN 37167; NDC 0869-0166-38 UPC 0 72785 13405 8

Product Quantity:

27,612 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1507-2022

Code Information:

Lot # 0562243, EXP 2/17/2024

Product Description:

Topcare health, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Cherry Flavor, 10 FL OZ (296 mL), Distributed By Topco Associates LLC Elk Grove Village, IL 60007; NDC 36800-164-38 UPC 0 36800 45530 6

Product Quantity:

18,588 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1508-2022

Code Information:

Lot # 0546394, EXP 9/29/2023

Product Description:

Walgreens, Dye-Free, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-8166-38 UPC 3 11917 20160 3 (green label)

Product Quantity:

29,172 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1509-2022

Code Information:

Lot # 0505266, EXP 10/17/2022

Product Description:

Walgreens, Dye-Free, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Grape Flavor, 10 FL OZ (296 mL), Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015; NDC 0363-7162-38 UPC 3 11917 20159 7 (purple label).

Product Quantity:

29,388 bottles

Reason for Recall:

Microbial contamination of non-sterile products.

Recall Number:

D-1510-2022

Code Information:

Lot # 0506255, EXP 10/24/2022

Class I Drugs Event

Event ID:

90785

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/22/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/19/2022

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

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

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

PROPOFOL Injectable Emulsion, 1 g/100 mL (10 mg/mL), packaged in 100 mL glass flip-top vial (NDC 0409-4699-54) further packaged in a tray of 10 vials (NDC Carton: 0409-4699-24), Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

Product Quantity:

5,390 vials

Reason for Recall:

Presence of particulate matter

Recall Number:

D-1540-2022

Code Information:

Lot#: EA7470, Exp 6/1/2023

Class II Drugs Event

Event ID:

90599

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/15/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/09/2022

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Vi-Jon, LLC
1 Swan Dr
Smyrna TN United States

Distribution Pattern:

Distributed Nationwide in the USA as well as Canada and Panama.

Associated Products

Product Description:

Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), a) CVS Health UPC 0 50428 33517 8 or UPC 0 50428 30594 2 Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895; b) Best Choice UPC 0 70038 20049 9 Proudly Distributed By: Valu Merchandisers, Co. 5000 Kansas Ave Kansas City, KS 66106; c) Care One UPC 3 41520 31322 6 Distributed By: Foodhold U.S.A., LLC, Landover, MD 20785 or Distributed By: Adusa Distribution, LLC Salisbury, NC 28147; d) Cariba UPC 6 46702 05701 2 Distributed by: Cariba International P.O. Box 1208 Safety Harbor, Florida 34595; e) Cruz Blanca UPC 3 0869-7403-08 2 or 3 08697 40308 2 Fabricado por Vi-Jon Inc. Smyrna, TN 37167 U.S.A. Dist.; f) Discount Drug Mart UPC 0 93351 02820 5 Distributed By: Discount Drug Mart 211 Commerce Drive, Medina, Ohio 44256; g) Equaline NDC 41163-709-38 UPC 0 41163 50067 9 Distributed by SUPERVALU INC. Eden Prairie, MN 55344 USA or Distributed By UNFI Providence, RI 02908 USA; h) Equate NDC 49035-506-38 UPC 6 81131 28714 2 Distributed By: Walmart Inc., Bentonville, AR 72716; i)

Exchange Select 6 14299 40420 5 Manufactured For Your Military Exchanges By: Vi-Jon Inc. 8515 Page Avenue, St. Louis, MO 63114; j) Family Wellness UPC 0 32251 58082 6 Distributed By: Midwood Brands, LLC 500 Volvo Parkway Chesapeake, VA 23330; k) Good Sense NDC 50804-166-38 UPC 8 46036 00737 4 Distributed By: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269 or Distributed by: Perrigo Direct, Inc. Peachtree City, GA 30269; l) Harris Teeter UPC 0 72036 72612 4 Proudly Distributed By: Harris Teeter, LLC Matthews, NC 28105; m) HEB UPC 0 41220 51086 3 Made With Pride & Care For H-E-B San Antonio, TX 78204; n) Health Mart NDC 62011-0380-1 UPC 0 52569 14215 8 Distributed by McKesson One Post Street, San Francisco, CA 94104; o) Kroger NDC 30142-899-38 UPC 0 41260 00182 6 Distributed By The Kroger CO Cincinnati, Ohio 45202; p) Leader Sugar-Free NDC 70000-0424-1 UPC 0 96295 13554 1 Distributed By Cardinal Health Dublin, OH 43017; q) Major NDC 0904-6787-44 UPC 3 09046 78744 0 Distributed By: Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152; r) Meijer NDC 41250-708-38 UPC 7 13733 45945 7 Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544; s) Premier Value UPC 8 40986 03530 2 Distributed by: Pharmacy Value Alliance LLC. 407 East Lancaster Avenue, Wayne, PA 19087; t) Publix NDC 56062-266-38 UPC 0 41415 50673 2 Distributed By Publix Super Markets, Inc. 3300 Publix Corporate Parkway, Lakeland, FL 33811; u) Quality Choice UPC 6 35515 90125 4 Distributed by C.D.M.A., Inc. 43157 W 9 Mile Rd Novi, MI 48375; v) Rexall UPC 0 72785 13418 8 Distributed By Dolgencorp. LLC 100 Mission Ridge Goodlettsville, TN 37072 or Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; w) Rite Aid NDC 11822-4330-2 UPC 0 11822 43300 6 Distributed By: Rite Aid 30 Hunter Lane Camp Hill, PA 17011; x) Signature Care NDC 21130-709-38 UPC 3 21130 77915 5 Distributed By: Better Living Brands LLC P.O. Box 99, Pleasanton, CA 94566-0009; y) Sound Body UPC 0 72785 11479 1 Manufactured for Big Lots by: Vi-Jon, Inc. 8515 Page Avenue; St. Louis, MO 63114; z) Sunmark NDC 70677-0051-1 UPC 0 10939 90844 5 Distributed By McKesson One Post Street, San Francisco, CA 94104 or Distributed by McKesson Corp., via Strategic Sourcing Services LLC, Memphis, TN 38141; aa) Swan NDC 0869-0166-38 UPC 0 72785 13405 8 Distributed by: Vi-Jon, Inc. One Swan Drive Smyrna, TN 37167; bb) Topcare health UPC 0 36800 45529 0 Distributed By Topco Associates, LLC. Elk Grove Village, IL 60007; cc) Up & Up NDC 11673-708-38 or NDC 11673-666-38 UPC 0 72785 12883 5 Dist. by Target Corp., Mpls., MN 55403; dd) Walgreens NDC 0363-8166-38 UPC 3 11917 20160 3 Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015

Product Quantity:

22,965,330 bottles

Reason for Recall:

CGMP Deviations

Recall Number:

D-1511-2022

Code Information:

All lots remaining within expiry.

Product Description:

Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Cherry Flavor, 10 FL OZ (296 mL), a) Best Choice UPC 0 70038 58790 3 Proudly Distributed By: Valu Merchandises, Co. 5000 Kansas Ave. Kansas City, KS 66106; b) Careone UPC 3 41520 00055 3 Distributed By: Foodhold U.S.A., LLC. Landover, MD 20785, Careone UPC 3 41520 00055 3 Distributed By: Adusa Distribution, LLC Salisbury, NC 28147; c) CVS Health UPC 0 50428 29733 9 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895, CVS Health UPC 0 50428 28515 2 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; d) Equaline NDC 41163-769-38 UPC 0 41163 50068 6 Distributed by Supervalu Inc. Eden Prairie, MN 55344 USA, Equaline NDC: 41163-769-38 UPC 0 41163 50068 6 Distributed By UNFI Providence, RI 02908; Equate NDC 49035-593-38 UPC 6 81131 28716 6 Distributed By: Walmart Inc., Bentonville, AR 72716; Family Wellness NDC 56319-164-38 UPC 0 32251 57788 8; e) GoodSense NDC 50804-164-38 UPC 8 46036 00739 8 Distributed By: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269, GoodSense NDC 508-164-38 UPC 8 46036 00739 8 Distributed by: Geiss, Destin & Dunn, Inc. A Perrigo Company, Peachtree City, GA 30269; f) HEB UPC 0 41220 51087 0 Made with Pride & Care For H-E-B San Antonio, TX 78204; g) Health Mart NDC 62011-0381-1 UPC 0 52569 14216 5 Distributed by McKesson One Post Street, San Francisco, CA 94104, Health Mart NDC 62011-0381-1 NDC 0 52569 14216 5 Distributed by McKesson Corp., via Strategic Sourcing Services LLC, Memphis, TN 38141; h) Leader Sugar-Free NDC 70000-0575-1 UPC 0 96295 14106 1 Distributed By Cardinal Health Dublin, Ohio 43017, Leader Sugar-Free NDC 70000-0576-1 UPC 0 96295 14105 4 Distributed By Cardinal Health Dublin, Ohio 43017; i) Meijer Sugar Free Low Sodium NDC 41250-769-38 UPC 7 13733 45944 0 Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544; j) Premier Value UPC 8 40986 03529 6 Distributed by: Pharmacy Value Alliance LLC 407 East Lancaster Avenue, Wayne, PA 19087; k) P NDC 56062-264-38 UPC 0 41415 50573 5 Distributed By Publix Super Markets, Inc. 3300 Publix Corporation Parkway, Lakeland, FL 33811; l) Quality Choice UPC 6 35515 90111 7 Distributed by C.D.M.A., Inc. 43157 W 9 Mile Rd Novi, MI 48375; Rexall UPC 0 72785 13416 4 Distributed By Dolgencorp, LLC 100 Mission Ridge Goodlettsville, TN 37072 USA, Rexall UPC 0 72785 13416 4 Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; m) Rite Aid NDC 11822-4303-2 UPC 0 11822 43303 7 Distributed By: Rite Aid 30 Hunter Lane Camp Hill, PA 17011; Signature Care NDC 21130-165-38 UPC 3 21130 78971 0 Distributed By Better Living Brands LLC P.O. Box 99, Pleasanton, CA 94566; n) Sunmark NDC 70677-0053-1 UPC 0 10939 91044 8 Distributed By McKesson One Post Street, San Francisco, CA 94104; o) Swan Very Low Sodium NDC 0869-0164-38 UPC 3 08690 69338 1 Distributed by: Vi-Jon, Inc. One Swan Drive Smyrna, TN 37167; p) TopCare Health NDC 36800-164-38 UPC 0 36800 45530 6 Distributed By Topco Associates LLC Elk Grove Village, IL 60007; q) Walgreens NDC 0363-8164-38 UPC 3 11917 20158 0 Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015 (red label), Walgreens NDC 0363-8164-38 UPC 3 11917 20158 0 Distributed By: Walgreen Co. 200 Wilmot RD., Deerfield, IL 60015

Product Quantity:

10,070,526

Reason for Recall:

CGMP Deviations

Recall Number:

D-1512-2022

Code Information:

All lots remaining within expiry.

Product Description:

Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Grape Flavor, 10 FL OZ (296 mL), a) Best Choice UPC 0 70038 66220 4 Proudly Distributed By: Valu Merchandisers, Co. 5000 Kansas Ave Kansas City, KS 66106; b) CVS Health UPC 0 50428 30745 8 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895, CVS Health UPC 0 50428 32503 2 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; c) Equate NDC 49035-592-38 UPC 6 81131 28715 9 Distributed By: Walmart, Inc. Bentonville, AR 72716; d) HEB UPC 0 41220 51088 7 Made With Pride & Care For H-E-B San Antonio, TX 78204; Kroger UPC 0 41260 00871 9 Distributed By The Kroger Co. Cincinnati, Ohio 45202; e) Leader NDC 70000-0576-1 UPC 0 96295 14105 4 Distributed By Cardinal Health Dublin, Ohio 43017; f) Rexall UPC 0 72785 13417 1 Distributed By Dolgencorp, LLC 100 Mission Ridge Goodlettsville, TN 37072 USA, Rexall UPC 0 72785 13417 1 Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; g) Walgreens NDC 0363-7162-38 UPC 3 11917 20159 7 Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015 (purple label), Walgreens NDC 0363-7162-38 UPC 3 11917 20159 7 Distributed By: Walgreen Co. 200 Wilmot RD., Deerfield, IL 60015 (blue label)

Product Quantity:

8,064,834

Reason for Recall:

CGMP Deviations;

Recall Number:

D-1513-2022

Code Information:

All lots remaining within expiry.

Class II Drugs Event

Event ID:

90798

Status:

Ongoing

Recall Initiation Date:

08/26/2022

Center Classification Date:

09/15/2022

Recalling Firm:

Carolina Infusion
95 Bees Creek Rd
Ridgeland SC United States

Distribution Pattern:

Nationwide in the USA.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

E-Mail

Associated Products

Product Description:

L-Carnitine 500 mg/mL Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1515-2022

Code Information:

Lot: 06132022@17; BUD: 02/15/2023

<p>Product Description: MIC/B12 25/50/50/1 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.</p> <p>Product Quantity: 3 vials</p> <p>Reason for Recall: Lack of Assurance of Sterility</p> <p>Recall Number: D-1516-2022</p> <p>Code Information: Lots: 08012022@4 BUD: 01/28/2023; 08082022@12 BUD: 02/04/2023</p>

<p>Product Description: MIC/B12/L-Carn (HD) 35/35/35/1/35 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.</p> <p>Product Quantity: 4 vials</p> <p>Reason for Recall: Lack of Assurance of Sterility</p> <p>Recall Number: D-1517-2022</p> <p>Code Information: Lots: 05042022@4 BUD: 10/31/2022; 06292022@9 BUD: 12/26/2022; 07262022@3 BUD: 01/22/2023</p>

<p>Product Description: Sermorelin Acetate 1 MG/ML Injectable, 9 ML syringes, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.</p> <p>Product Quantity: 8 syringes</p> <p>Reason for Recall: Lack of Assurance of Sterility</p> <p>Recall Number: D-1518-2022</p> <p>Code Information: Lots: 08012022@14 BUD: 08/31/2022; 08192022@7 BUD: 09/23/2022</p>
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<p>Product Description: Semaglutide/Cyanocobalamin 5/2 MG/ML Injectable, 0.2 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.</p> <p>Product Quantity: 24 syringes</p> <p>Reason for Recall: Lack of Assurance of Sterility</p> <p>Recall Number: D-1519-2022</p> <p>Code Information: Lots: 08122022@8 BUD: 09/11/2022; 08162022@3 BUD: 09/15/2022</p>
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<p>Product Description: Semaglutide/Cyanocobalamin 10/2 MG/ML Injectable, 0.4 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.</p> <p>Product Quantity: 4 syringes</p> <p>Reason for Recall: Lack of Assurance of Sterility</p> <p>Recall Number: D-1520-2022</p>

Code Information:

Lot: 08152022@14 BUD: 09/14/2022

Product Description:

Semaglutide/Cyanocobalamin 24/2 MG/ML Injectable, 0.4 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

4 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1521-2022

Code Information:

Lot: 08172022@1 BUD: 09/16/2022

Product Description:

TEST CYP (Grapeseed) 200 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1522-2022

Code Information:

Lots: 06132022@5 BUD: 09/11/2022; 08082022@17 BUD: 11/06/2022

Product Description:

TEST CYP/DHEA (Sesame Oil) 100 MG/2.5 MG/ML Injection, 3 ML and 6 ML vials, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

3 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1523-2022

Code Information:

Lots: 07182022@9 BUD: 10/16/2022; 07272022@15 BUD: 10/25/2022

Product Description:

TEST CYP/DHEA (Sesame) 200 MG/2.5 MG/ML Injectable, 10 ML vial, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

348 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1524-2022

Code Information:

Lots: 06012022@1, 06012022@2 BUD: 08/30/2022; 06032022@1, 06032022@2, 06032022@13 BUD: 09/01/2022; 06062022@7, BUD: 09/04/2022; 06072022@3, 06072022@4 BUD: 09/05/2022; 06082022@1, 06082022@2, 06082022@4 BUD: 09/06/2022; 06102022@8, BUD: 09/08/2022; 09/11/2022; 06132022@1, 06132022@7, 06132022@14, 06132022@15, BUD: 09/11/2022; 06142022@7, 06142022@8, 06142022@15, BUD: 09/12/2022; 06152022@2, BUD: 09/13/2022; 06172022@4, BUD: 09/15/2022; 06202022@9, 06202022@10, 06202022@23, BUD: 09/18/2022; 06212022@2, BUD: 09/19/2022; 06222022@2, 06222022@3, BUD: 09/20/2022; 06242022@4, 06242022@5, BUD: 09/22/2022; 06272022@3, BUD: 09/25/2022; 06292022@5, 06292022@6, BUD: 09/27/2022; 07012022@11, 07012022@12, BUD: 09/29/2022; 07052022@3, 07052022@4, BUD: 10/03/2022; 07062022@4, 07062022@5, 07062022@10, BUD: 10/04/2022; 07082022@4, 07082022@5, BUD: 10/06/2022; 07092022@12, 07092022@13, BUD: 10/07/2022; 07112022@16, 07112022@17, BUD: 10/09/2022; 07122022@14, 07122022@15, BUD: 10/10/2022; 07132022@5, BUD: 10/11/2022; 07152022@11, 07152022@12, BUD: 10/13/2022; 07182022@2, 07182022@3, BUD: 10/16/2022;

07192022@10, 07192022@11, 07192022@22, BUD: 10/17/2022; 07202022@9, 07202022@10, 07202022@11, BUD: 10/18/2022; 07222022@2, BUD: 10/20/2022; 07252022@18, 07252022@19, BUD: 10/23/2022; 07272022@12, BUD: 10/25/2022; 07282022@5, BUD: 10/26/2022; 07292022@4, 07292022@5, BUD: 10/27/2022; 08012022@6, 08012022@7, BUD: 10/30/2022; 08022022@1, BUD: 10/31/2022; 08032022@8, 08032022@12, 08032022@13, BUD: 11/01/2022; 08052022@5, 08052022@6, BUD: 11/03/2022; 08082022@9, 08082022@15, 08082022@16, BUD: 11/06/2022; 08092022@10, 08092022@11, BUD: 11/07/2022; 08122022@5, 08122022@6, BUD: 11/10/2022; 08152022@16, 08152022@17, 08152022@20, BUD: 11/13/2022; 08192022@24, 08192022@5, 08192022@6, 08192022@25, BUD: 11/17/2022; 08222022@9, 08222022@10, BUD: 11/20/2022; 08232022@15, 08232022@18, BUD: 11/21/2022

Product Description:

TEST CYP/PROP (50:50) 100 MG/100 MG/ML Injectable, 12.6 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1525-2022

Code Information:

Lot: 07052022@1 BUD: 10/08/2022

Product Description:

TRI-MIX 30/1/10 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

16 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1526-2022

Code Information:

Lots: 06282022@1, BUD: 08/27/2022; 06292022@8, BUD: 08/28/2022; 07012022@19, BUD: 08/30/2022; 07012022@3, BUD: 08/30/2022; 07122022@8, BUD: 09/10/2022; 07132022@9, BUD: 09/11/2022; 07192022@1, BUD: 09/17/2022; 07292022@9, BUD: 09/27/2022; 08032022@10, BUD: 10/02/2022; 08092022@2, BUD: 10/08/2022; 08102022@1, 08102022@6, 08102022@7, BUD: 10/09/2022; 08152022@5, BUD: 10/14/2022; 08192022@1, 08192022@10, BUD: 10/18/2022

Product Description:

TRI-MIX 30/1/20 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

7 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1527-2022

Code Information:

Lots: 06272022@6 BUD: 08/26/2022; 07212022@3 BUD: 09/19/2022; 07292022@11 BUD: 09/27/2022; 08052022@7 BUD: 10/04/2022; 08102022@5 BUD: 10/09/2022; 08122022@14 BUD: 10/11/2022; 08172022@7 BUD: 10/16/2022

Product Description:

TRI-MIX 30/1/40 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1528-2022

Code Information:

Lots: 07052022@8, BUD: 09/03/2022; 07292022@10, BUD: 09/27/2022

Product Description:

TRI-MIX 30/1/60 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

3 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1529-2022

Code Information:

Lots: 07012022@6, BUD: 09/20/2022; 07192022@16, BUD: 09/17/2022; 07012022@4, BUD: 08/30/2022

Product Description:

TRI-MIX 30/2/20 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

11 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1530-2022

Code Information:

Lots: 07052022@10, BUD: 09/03/2022; 07052022@16, BUD: 09/03/2022; 07122022@11, BUD: 09/08/2022; 07182022@17, BUD: 09/16/2022; 07202022@6, BUD: 09/18/2022; 07252022@9, BUD: 09/23/2022; 07292022@2, BUD: 09/27/2022; 07292022@13, BUD: 09/27/2022; 08122022@9, BUD: 10/11/2022; 08162022@2, BUD: 10/15/2022; 08262022@1, BUD: 10/25/2022

Product Description:

TRI-MIX 30/2/40 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

2 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1531-2022

Code Information:

Lots: 07152022@4, BUD: 09/13/2022; 08152022@15, BUD: 10/14/2022

Product Description:

TRI-MIX 50/2.5/25 Injectable, 2 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1532-2022

Code Information:

Lot: 07052022@2, BUD: 09/03/2022

Product Description:

QUAD-MIX 30/2/60/0.15 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1533-2022

Code Information:

Lot: 08022022@12, BUD: 10/01/2022

Product Description:

QUAD-MIX 30MG/3MG/60MCG/0.2 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.

Product Quantity:

1 vial

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1534-2022

Code Information:

Lot: 08082022@3, BUD: 10/07/2022

Class II Drugs Event

Event ID:

90803

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/16/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States**Distribution Pattern:**

Nationwide in the US.

Associated Products

Product Description:

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product), 15 mg, Rx Only, 100 tablets per bottle, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0555-0777-02.

Product Quantity:

83,703 bottles

Reason for Recall:

Labeling: Label Error on Declared Strength; A sealed 100-count bottle labeled with 15 mg actually contained 100 tablets of 20 mg strength of the drug product.

Recall Number:

D-1539-2022

Code Information:

Lot #: 100023340, Exp 10/2024

Class II Drugs Event

Event ID:

90827

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

09/01/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

SUPERIOR GLOVE WORKS, LTD.
36 Vimy St
Acton Canada

Distribution Pattern:

Nationwide in the US.

Associated Products

Product Description:

Synergy Hand Sanitizer, Non-Sterile Solution to help reduce bacteria that can potentially cause disease, For use when soap and water are not available, Alcohol 80% Topical Solution, Antiseptic, 8.5 oz./ 250 mL bottles, Made and Distributed by: Superior Glove Works Ltd., 36 Vimy Street, Acton, Ontario, L7J 1S1, Canada, Made in Canada, UPC: 779406201594.

Product Quantity:

7,296 bottles

Reason for Recall:

CGMP Deviations: FDA analysis found product to contain acetaldehyde impurity and the Sum of All Impurities, above specification limits.

Recall Number:

D-1537-2022

Code Information:

Lot # 200513TA, Exp. 05/2023.

Class II Drugs Event

Event ID:

90854

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/27/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Pine Pharmaceuticals, LLC
355 Riverwalk Pkwy
Tonawanda NY United States

Distribution Pattern:

Product was distributed to direct accounts in AL, CA, NC and NY

Associated Products

Product Description:

Bupivacaine HCl 0.375% w/v and Lidocaine HCl 2% w/v Solution for Retrobulbar or Peribulbar Injection; packaged in a) 10 mL prefilled syringe, Item# 803, barcode 6919408031; b) 5 mL prefilled syringe, Item# 933, barcode 6919409331, Rx only, Pine Pharmaceuticals, 355 Riverwalk Parkway, Tonawanda, NY 14150.

Product Quantity:

a) 920 syringes; b) 3263 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-1514-2022

Code Information:

Lot #s: a) 58366, exp. date 09/26/2022; 60247, exp. date 12/04/2022; b) 54825, exp. date 08/10/2022; 57583, exp. date 08/22/2022; 59343, exp. date 10/30/2022; 60355, exp. date 10/11/2022

Class II Drugs Event

Event ID:

90859

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/13/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:

Product was distributed to major distributors/wholesalers nationwide.

Associated Products

Product Description:

Lisinopril Tablets USP, 10 mg, 1000-count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited, Nagpur- 441 108, India. NDC 68180-980-03

Product Quantity:

11,802 1000-count bottles

Reason for Recall:

Presence of Foreign Substance: Foreign material (metal piece) embedded in one tablet.

Recall Number:

D-1536-2022

Code Information:

Lot # Q201182, exp. date March 2024

Class II Drugs Event

Event ID:

90869

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/12/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:

Physicians and Medical Facilities in GA and ID

Associated Products

Product Description:

Triamcinolone Acetonide cream, 0.1%, 80 g tube, Rx only, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534, Dist. By Perrigo, Allegan, MI 49010, NDC 72189-330-80.

Product Quantity:

20 tubes

Reason for Recall:

CGMP Deviations: Product complaints reporting the product to have a gritty texture and lack of effectiveness.

Recall Number:

D-1535-2022

Code Information:

Lot: 12JY2216, Exp. 2/29/24

Class II Drugs Event

Event ID:

90873

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

09/15/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/15/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:

Distributed to two direct accounts in PA and AK.

Associated Products

Product Description:

Lisinopril 10 mg tablets, 30-count Blister Card, Rx Only, MFG: Lupin Pharma, Baltimore, MD Repackaged by: RemedyRepack Inc, Indiana PA. Original NDC# 68180-0980-03, Repackaged NDC# 70518-0468-00

Product Quantity:

1,699 blister cards/30 tablets each

Reason for Recall:

Presence of Foreign Substance: Foreign material (metal piece) embedded in one tablet.

Recall Number:

D-1538-2022

Code Information:

Lot # J0636336-073022, J0637605-080422, Exp. date 08/31/2023

Not Yet Classified Drugs Event

Event ID:

90638

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

07/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:

Edgewell Personal Care Brands, LLC
6 Research Dr
Shelton CT United States

Distribution Pattern:

USA nationwide.

Associated Products

Product Description:

Banana Boat Hair & Scalp Defense, Clear Sunscreen Spray SPF 30, packaged in aluminum spray can, Net Wt 6 oz., Distributed by: Edgewell Personal Care Brands, LLC, Shelton, CT 06484, UPC 0 7965604041 8

Product Quantity:

139,680 aluminum spray cans

Reason for Recall:

Chemical contamination: presence of Benzene

Recall Number:

Code Information:

Lot #: 20016AF, Exp 12/22; 20084BF, Exp 2/23; 21139AF, Exp 4/24