Enforcement Report - Week of March 2, 2022

Class II Drugs Event

Event ID:
88905

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Perrigo Company PLC
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Acetaminophen Oral Suspension Grape Flavor, 160 mg per 5 mL, 16 fl oz (473 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 50941-009-43

Product Quantity:
14,868 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0579-2022

Code Information:
Batch: 1AK1031, Exp 12/31/2022

Product Description:
Children's Pain & Fever Bubblegum Flavored Acetaminophen Suspension (160mg/5ml), 4 fl oz (118 mL) per bottle, Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716. NDC: 49035-313-26

Product Quantity:
117552 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0580-2022

Code Information:
Batch: 1BK0784, Exp 12/31/2022; 1CK0997, 1CK1083, Exp 01/31/2023

Product Description:
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152. NDC: 0536-1321-97

Product Quantity:
4,992 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0581-2022

Code Information:
Batch: 1BK0960, Exp 12/31/2022

Product Description:
Children's Cherry Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 45802-203-26

Product Quantity:
4,176 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0582-2022

Code Information:
Batch: 1GK0903, Exp 01/31/2023

Product Description:
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015. NDC: 0363-0971-26

Product Quantity:
14,064 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0583-2022

Code Information:
Batch: 1DK0917, 1GK0905, Exp 01/31/2023

Product Description:
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, Distributed by Target Corporation, Minneapolis, MN 55403. NDC: 11673-133-16

Product Quantity:
22,140 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0584-2022

Code Information:
Batch: 1CK0907, Exp 01/31/2023

Product Description:
Infant's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC: 59779-946-16

Product Quantity:
37,152 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0585-2022

Code Information:
Batch: 1CK1276, 1FK1184, 1GK0821 and 1EK1046, Exp 02/28/2023

Product Description:
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202. NDC: 30142-818-26

Product Quantity:
3,120 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0586-2022

Code Information:
Batch: 1BK1045, Exp 12/31/2022

Product Description:
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed By Perrigo, Allegan, MI 49010. NDC: 0113-8959-26

Product Quantity:
2,832 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0587-2022

Code Information:
Batch: 1BK1045, Exp 12/31/2022

Product Description:
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC: 30142-818-26

Product Quantity:
20,448 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0588-2022

Code Information:
Batch: 1BK1045, Exp 12/31/2022

Product Description:
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716. NDC: 49035-959-26

Product Quantity:
30,144 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0589-2022

Code Information:
Batch: 1BK1045, Exp 12/31/2022

Product Description:
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC, 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC: 55910-251-26

Product Quantity:
16,992 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0590-2022

Code Information:
Batch: 1CK1001, Exp 12/31/2022

Product Description:
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by Target Corp., Minneapolis, MN 55403 NDC: 11673-130-26

Product Quantity:
26,832 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0591-2022

Code Information:
Batch: 1CK1146, Exp 02/28/2023

Product Description:
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by: Walmart, Inc., Bentonville, AR 72716. NDC: 49035-042-26

Product Quantity:
111,888 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0592-2022

Code Information:
Batch: 1BK0962, Exp 12/31/2022, 1CK0999, Exp 01/31/2023

Product Description:
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, MADE WITH PRIDE & CARE FOR H-E-B SAN ANTONIO, TX 78204. NDC: 37808-759-26

Product Quantity:
3,840 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0593-2022

Code Information:
Batch: 1GK0905, Exp 01/31/2023

Product Description:
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Target Corporation, Minneapolis, MN 55403. NDC: 11673-759-26

Product Quantity:
14,688 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0594-2022

Code Information:
Batch: 1FK1252, 1GK0905, Exp 01/31/2023

Product Description:
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC: 30142-766-16

Product Quantity:
1,296 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0595-2022

Code Information:
Batch: 1CK1274, Exp 02/28/2023

Product Description:
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC: 30142-766-16

Product Quantity:
5,184 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0596-2022

Code Information:
Batch: 1CK1274, Exp 02/28/2023

Product Description:
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentoneville, AR 72716. NDC: 49035-766-16

Product Quantity:
55,656 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0597-2022

Code Information:
Batch: 1CK1274, Exp 02/28/2023

Product Description:
Infant's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716. NDC: 49035-946-16

Product Quantity:
68,688 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0598-2022

Code Information:
Batches: 1FK1027, 1FK1184, 1EK1046, Exp 02/28/2023

Product Description:
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), two 4 FL OZ (118 mL) bottles per pack, Distributed by Walmart Inc., Bentonville, AR 72716. NDC: 49035-313-26

Product Quantity:
83760 packs

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0599-2022

Code Information:
Batch: 1BK0794, Exp 12/31/2022, 1BK1035, Exp 01/31/2023

Product Description:
Children's Pain & Fever Acetaminophen, 160 mg per 5 mL Oral Suspension combo pack. DS SR APAP 160MG CHLD BBGM/DF CHRY/GRP. UPC: 3 70030 11637 9

Product Quantity:
561 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0600-2022

Code Information:
Batch: 1EV1874, Exp 11/02/2022

Product Description:
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 11673-105-26

Product Quantity:
4,992 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0601-2022

Code Information:
Batch: 1CK0998, Exp 01/31/2023

Product Description:
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 0113-0020-26

Product Quantity:
3,024 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0602-2022

Code Information:
Batch: 1CK0963, Exp 12/31/2022

Product Description:
Maximum Strength Plus Menthol No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: AMAZON.COM SERVICES LLC 410 TERRY AVENUE N.SEATTLE, WA 98109. NDC: 72288-703-10

Product Quantity:
37,104 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0603-2022

Code Information:
Batch: 1FK1251, Exp 02/28/2023; 1BK0716, Exp 12/31/2022

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, Packaged by Perrigo Company for: Big Lots Stores, Inc., P.O. Box 28523, Columbus, OH 43228-0523. NDC: 50594-719-10

Product Quantity:
3,168 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0604-2022

Code Information:
Batch: 1BK0827, Exp 12/31/2022

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY FOODHOLD U.S.A., LLC, LANDOVER, MD 20785. NDC 41520-108-10

Product Quantity:
7,200 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0605-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022; 1FK1251, Exp 02/28/2023

Product Description:
Severe Congestion No Drip Nasal Spray Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC, 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-511-10

Product Quantity:
21,4824 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0606-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022); 1CK0899, Exp 01/31/2023; 1FK1163, Exp 01/31/2023

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY FOODHOLD U.S.A., LLC, LANDOVER, MD 20785. NDC 41520-108-10

Product Quantity:
3,192 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0607-2022

Code Information:
Batch: 1BK0716; Exp 12/31/2022); 1FK1251, Exp 02/28/2023

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011. NDC 11822-6378-1

Product Quantity:
9,888 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0608-2022

Code Information:
Batch: 11BK0827, Exp 12/31/2022

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99, PLEASANTON, CA 94566-0009. NDC 21130-813-10

Product Quantity:
14,784 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0609-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022; 1FK1251, 1HK1196, Exp 02/28/2023

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Distributed by SUPERVALU INC., Eden Prairie, MN 55344 USA. NDC 41163-343-10

Product Quantity:
2,664 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0610-2022

Code Information:
Batch: 1FK1251, Exp 02/28/2023

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Dist. by Target Corp., Mpls., MN 55403. NDC 11673-935-10

Product Quantity:
89,208 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0611-2022

Code Information:
Batch: 1BK0912, Exp 12/31/2022; 1FK1251, Exp 02/28/2023

Product Description:
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY TOPCO ASSOCIATES LLC., ELK GROVE VILLAGE, IL 60007. NDC 36800-907-10

Product Quantity:
19,584 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0612-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: AMAZON.COM SERVICES LLC, 410 TERRY AVENUE N. SEATTLE, WA 9810. NDC 72288-388-10

Product Quantity:
1,296 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0613-2022

Code Information:
Batch: 1BK0964R, Exp 01/31/2023

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: AMAZON.COM SERVICES LLC, 410 TERRY AVENUE N. SEATTLE, WA 9810. NDC 72288-388-10

Product Quantity:
26,448 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0614-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022); 1BK0964R, Exp 01/31/2023

Product Description:
No Drip Nasal Mist, Oxymetazoline HCl 0.05% Nasal decongestant, 1 FL Oz (30 mL) per bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC 59779-388-10

Product Quantity:
64,512 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0615-2022

Code Information:
Batch: 1FK1164, Exp 01/31/2023

Product Description:
Maxiumum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-623-10

Product Quantity:
123,408 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0616-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022); 1FK1232, 1BK0964, Exp 01/31/2023

Product Description:
Nasal Spray Decongestant, No Drip, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10

Product Quantity:
7,632 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0617-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022

Product Description:
Soothing 12 Hour Nasal Decongestant Spray No Drip, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Distributed By MAJOR PHARMACEUTICALS, 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152. NDC 0904-6761-30

Product Quantity:
41,472 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0618-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022; 1FK1164, Exp 01/31/2023

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-388-10

Product Quantity:
10,800 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0619-2022

Code Information:
Batch: 1FK1164, Exp 01/31/2023

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10

Product Quantity:
3,744 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0620-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011. NDC 11822-6319-1

Product Quantity:
15,264 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0621-2022

Code Information:
Batch: 1BK0964, Exp 01/31/2023; 1FK1164, Exp 01/31/2023

Product Description:
No Drip Nasal Decongestant, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99, PLEASANTON, CA 94566-0009. NDC 21130-801-10

Product Quantity:
11,088 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0622-2022

Code Information:
Batch: 1BK0964, Exp 01/31/2023

Product Description:
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, Distributed by SUPERVALU INC., Eden Prairie, MN 55344 USA. NDC 41163-703-10

Product Quantity:
1,560 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0623-2022

Code Information:
Batch: 1BK0964, Exp 01/31/2023

Product Description:
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10

Product Quantity:
36,864 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0624-2022

Code Information:
Batch: 1BK0826, Exp 12/31/2022

Product Description:
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007. NDC 36800-388-10

Product Quantity:
13,824 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0625-2022

Code Information:
Batch: 1FK1233, Exp 01/31/2023

Product Description:
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716. NDC 49035-388-10

Product Quantity:
178,128 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0626-2022

Code Information:
Batch: 1CK0897, 1FK1233, 1FK1232, Exp 01/31/2023

Product Description:
Sinus Severe, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-696-10

Product Quantity:
79,776 botles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0627-2022

Code Information:
Batch: 1BK0931, Exp 12/31/2022; 1CK0900, Exp 01/31/2023; 1HK1196, Exp 02/28/2023

Product Description:
Maximum Strength Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL) per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-989-10

Product Quantity:
2,302 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0628-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022

Product Description:
Maximum Strength Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL) per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-989-10

Product Quantity:
144 bottles

Reason for Recall:
CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.

Recall Number:
D-0629-2022

Code Information:
Batch: 1BK0716, Exp 12/31/2022

Class II Drugs Event

Event ID:
89545

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RISING PHARMACEUTICALS
2 Tower Center Blvd
East Brunswick NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Methylphenidate Hydrochloride Chewable Tablets, 2.5 mg, 100-count bottle, Rx Only, Manufactured for: Rising Pharmaceuticals Inc., Saddle Brook, NJ 07863, NDC 64980-221-01

Product Quantity:
2220 100-count bottles

Reason for Recall:
Failed Tablet Specifications: Recall of this drug product was voluntarily initiated by the manufacturer due to a market complaint, which stated that a tablet in the sealed bottle was twice larger in size when compared to the remaining tablets. This complaint is second of its kind.

Recall Number:
D-0573-2022

Code Information:
lot# 25910009, Exp 01/2023

Class II Drugs Event

Event ID:
89547

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Professional Disposables International, Inc.
2 Nice Pak Park
Orangeburg NY United States

Distribution Pattern:
Product was distributed nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Maxi Swabstick, 3.15% w/v and 70% v/v, packaged as a) One Maxi Swabstick, 0.172 fl. Oz. (5.1 mL) Each in a pouch, 30 Individual Maxi Swabsticks per carton, 10 boxes of 30 Individual Swabsticks per case, NDC 10819-

4076-4, REORDER NO. S41950; b) One Maxi Swabstick, 0.172 fl. Oz. (5.1 mL) Each in a pouch, 300 Individual Swabsticks per case, NDC 10819-4076-3, REORDER NO. S27350; Professional Disposables International, Inc., Orangeburg, NY 10962-1376.

Product Quantity:
a) 9518 cases; b) 3347 cases

Reason for Recall:
cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.

Recall Number:
D-0570-2022

Code Information:
Lot #: a) 12000315, Exp Feb 2022; 12000700, Exp Mar 2022; 12001112 LE, Exp Jun 2022; 12001214, Exp Jul 2022; 12001362, 12001406, Exp Aug 2022; 12001628, Exp Sep 2022; 12001856, Exp Oct 2022; 12002103, Exp Dec 2022; 12002113, 12100024, Exp Jan 2023; 12100226, 12100227, Exp Feb 2023; 12100443, 12100503, Exp Mar 2023; 12100516, 12100517, Exp Apr 2023; 12100748, 12100756, Exp May 2023; b) 12001113 LE, Exp Jun 2022; 12001289, 12001240, Exp Jul 2022; 12002104, Exp Dec 2022; 12100025, Exp Jan 2023; 12100405, Exp Mar 2023; 12100674, Exp Apr 2023; 12100779, Exp May 2023

Product Description:
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Swab, 3.15% w/v and 70% v/v, packaged as a) One Swab, 0.034 fl. Oz. (1 mL) Each in a pouch, 100 Individual Swabs per carton, 10 boxes of 100 Individual Swabs per case, REORDER NO. B10800, NDC 10819-1080-1; b) One Swab, 0.034 fl. oz. (1 mL) Each in a pouch, 3000 Individual Swabs per case, REORDER NO. B11400, NDC 10819-1080-2; Professional Disposables International, Inc., Orangeburg, NY 10962-1376.

Product Quantity:
a) 160531 cases; b) 16123 cases

Reason for Recall:
cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.

Recall Number:
D-0571-2022

Code Information:
Lot #: a) 12000165, 12000166, 12000382, Exp Feb 2022; 12000228, 12000381, 12000383, 12000577, 12000578, 12000579, 12000661, 12000662, Exp Mar 2022; 12000659, 12000660, Exp Apr 2022; 12001060, 12001061, 12001062, 12001100 LE, 12001101 LE, Exp Jun 2022; 12001233, 12001234, 12001235, 12001236, Exp Jul 2022; 12001351, 12001394, 12001395, 12001396, 12001397, 12001398, 12001399, Exp Aug 2022; 12001632,12001633, 12001634, 12001635, 12001636, Exp Sep 2022; 12001637, 12001638, 12001639, 12001640, 12001641, 12001721, 12001791, Exp Oct 2022; 12001792, 12001793, 12001794, 12001962, Exp Nov 2022; 12002039, 12002040, 12100014, 12100015, 12100016, 12100017, 12100035, 12100036, 12100037, 12100074, 12100183, 12100184, Exp Jan 2023; 12100018, 12100185, 12100186, 12100192, 12100193, 12100194, 12100195, 12100241, 12100242, 12100243, 12100244, 12100245, 12100246, 12100247, 12100277, Exp Feb 2023; 12100312, 12100313, 12100347, 12100348, 12100349, Exp Mar 2023; 12100350, 12100351, 12100543, 12100638, Exp Apr 2023; 12100541, 12100542, 12100639, 12100732, 12100733, 12100753, 12100754, Exp May 2023; 12100755, 12100790, 12100791, 12100824, Exp Jun 2023; b) 12000194, 12000195, Exp Feb 2022; 12000500, 12000570, 12000594, 12000698, Exp Mar 2022; 12001058, 12001059, 12001069, 12001108 LE, 12001109 LE, 12001110 LE, Exp Jun 2022; 12001111 LE, 12001225, 12001226, 12001227, 12001228, 12001229, 12001230, Exp Jul 2022; 12001393, 12001522, Exp Aug 2022; 12001734, 12001735, 12001736, 12001737, Exp Oct 2022; 12001854, Exp Nov 2022; 12002033, 12002035, 12002045, 12002046, Exp Dec 2022; 12100019, 12100020, 12100021, 12100022, 12100096, 12100097, 12100098, 12100099, Exp Jan 2023; 12100196, 12100197, 12100251, 12100252, 12100253, 12100254, 12100255, 12100256, 12100257, 12100346, Exp Feb 2023; 12100363,12100364, 12100365, 12100366, Exp Mar 2023; 12100518, 12100519, 12100520, 12100521, Exp Apr 2023; 12100691, 12100693, Exp May 2023

Product Description:
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Swabstick, 3.15% w/v and 70% v/v, packaged as a) One Swabstick, 0.054 fl. oz. (1.6 mL) Each in a pouch, NDC 10819-4077-1; 50 Individual Swabsticks per carton, 10 boxes of 50 Individual Swabsticks per case, REORDER NO. S40750, NDC 10819-4077-4; b) One Swabstick, 0.054 fl. Oz. (1.6 mL) Each in a pouch, 500 Individual Swabsticks per case, REORDER NO. S32450, NDC 10819-4077-2; c) One Swabstick, 0.054 fl. Oz. (1.6 mL) Each in a pouch, 500 Individual Swabsticks per case, REORDER NO. S42850, NDC 10819-4077-3; Professional Disposables International, Inc., Orangeburg, NY 10962-1376.

Product Quantity:
a) 28201 cases; b) 7579 cases; c) 8882 cases

Reason for Recall:
cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.

Recall Number:
D-0572-2022

Code Information:
Lot #: a) 12000203, 12000204, Exp Mar 2022; 12001114 LE, Exp Jun 2022; 12001115 LE, 12001117 LE, Exp Jul 2022; 12001313, 12001407, 12001408, Exp Aug 2022; 12001498, 12001499, 12001500, 12001629, 12001630, Exp Sep 2022; 12002070, 12002114, Exp Dec 2022; 12100106, 12100107, 12100223, Exp Feb 2023; 12100224, 12100225, 12100354, 12100513, Exp Mar 2023; 12100514, 12100515, 12100605, 12100628, Exp Apr 2023; 12100629, 12100630, Exp May 2023; b) 12000332, Exp Feb 2022; 12000484, Exp Mar 2022; 12001116 LE, Exp Jul

2022; 12001312, Exp Aug 2022; 12001730, Exp Oct 2022; 12002071, 12100105, Exp Jan 2023; 12100222, Exp Mar 2023; 12100635, 12100636, Exp Jun 2023; c) 12000728, Exp Apr 2022; 12001119 LE, Exp Jul 2022; 12001631, Exp Oct 2022; 12001811, Exp Nov 2022; 12002115, 12002116, Exp Jan 2023; 12100221, Exp Feb 2023; 12100633, Exp May 2023; 12100634, 12100774, 12100817, Exp Jun 2023

Class II Drugs Event

Event ID:
89635

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2022

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmasol Corporation
1 Norfolk Ave
South Easton MA United States

Distribution Pattern:
Product was distributed to a client in Colorado.

Associated Products

Product Description:
Lung Cleaner (saline eucalyptus) inhaler, 37 oz cans, Manufactured For: The Lung Cleaner LLC Boulder, CO 80302

Product Quantity:
5,004 cans of propellent

Reason for Recall:
cGMP deviations

Recall Number:
D-0574-2022

Code Information:
Lot #: 33748

Class III Drugs Event

Event ID:
89447

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Azacitidine, 1,00mg/Vial, One Single-dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-305-62

Product Quantity:
68061 vials

Reason for Recall:
Failed stability specifications

Recall Number:
D-0575-2022

Code Information:
Lot #: H200101, H200102, H200099, H200100 & H200106, Exp 8/1/2023; H210015, H210014 & H210013, Exp 11/1/2023; H210086, Exp 12/1/2023; H210130, Exp 1/1/2024; H210171, H210172, H210173, H210174, Exp 2/1/2024; H210196 & H210197, Exp 3/1/2024; H210283 & H210282, Exp 4/1/2024; H210382, H210381, H210419 & H210420, Exp 7/1/2024, H210445, Exp 8/1/2024.

Product Description:
Azacitidine, 100mg/vial, One Single-dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-465-62

Product Quantity:
18261 vials

Reason for Recall:
Failed stability specifications

Recall Number:
D-0576-2022

Code Information:
Lot#: H200107, Exp 8/1/2023; H200154, Exp 9/1/2023; H210020, Exp 11/1/2023; H210055, Exp 12/1/2023; H210129, Exp 1/1/2024, H210288, Exp 4/1/2024.

Product Description:
Bortezomib, 3.5 mg/vial, Single-Dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-865-60

Product Quantity:
2,980 vials

Reason for Recall:
Failed stability specifications

Recall Number:
D-0577-2022

Code Information:
Lot # H210233, Exp 3/1/2023

Class III Drugs Event

Event ID:
89599

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/18/2022

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

Recalling Firm:
BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy
7802 E Telecom Pkwy
Temple Terrace FL United States

Distribution Pattern:
Florida

Associated Products

Product Description:
Norepinephrine bitartrate 16 mg in 250 mL NaCl 0.9%, packaged in IV bags, Rx only, BayCare Central Pharmacy 7802 E. Telecom Parkway Temple Terrace, FL 33637 (813) 901-6392

Product Quantity:
1157 bags

Reason for Recall:
Subpotent drug

Recall Number:
D-0569-2022

Code Information:
Lot #: Nore1620220111, Nore1620220113, Nore1620220118, Nore1620220125, Nore1620220127, Nore1620220202, Exp 3/31/22

Class III Drugs Event

Event ID:
89626

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/28/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Sapropterin Dihydrochloride Powder for Oral Solution, 100 mg, 30 individual packets per carton, Rx Only, Dr. Reddy's, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC: 43598-477-11 (packet), 43598-477-30 (carton).

Product Quantity:
340 packets

Reason for Recall:
Subpotent Drug: Out-of-specification results observed in Assay in sapropterin dihydrochloride powder 100mg.

Recall Number:
D-0640-2022

Code Information:
T2100891, Exp. 02/28/2024

Not Yet Classified Drugs Event

Event ID:
89503

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
SHUZY ROCK INC
161 Helen St
South Plainfield NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 65%), plastic bottles packaged as (a) 2 OZ / 60ML, UPC 8 19192 02865 1; (b) 4 OZ, 118 ML, UPC 8 19192 02826 2; (c) 16 OZ, 473 ML, UPC 8 19192 02874 3; (d) 1 gallon, UPC 8 19192 02830 9; Premium Nature, South Plainfield, NJ.

Product Quantity:
2,095,567 bottles

Reason for Recall:
Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.

Recall Number:

Code Information:
All lots within expiry and labelled as 'Made in the USA'

Product Description:
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 70%), plastic bottle packaged as (a) 8 OZ, UPC 8 19192 02866 8; (b) 16 OZ, UPC 8 19192 02874 3; Premium Nature, South Plainfield, NJ.

Product Quantity:
487,000 bottles

Reason for Recall:
Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.

Recall Number:

Code Information:
All lots within expiry and labelled as 'Made in the USA'

Not Yet Classified Drugs Event

Event ID:
89606

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Positive Health
1013 Centre Rd Suite 403B
Wilmington DE United States

Distribution Pattern:
Product was distributed nationwide via the internet through Amazon Marketplace.

Associated Products

Product Description:
RISE UP RED EDITION Capsules, 650 mg, 10-count blisters packaged in a carton, ASIN B08JCWG84D, barcode X002NI8PE1.

Product Quantity:
5,500 cartons

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared tadalafil, an ingredient found in FDA approved products

for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
Lot # 48658908, Exp. date 09/09/2023