

Enforcement Report - Week of October 24, 2018

Class I Drugs Event

Event ID:

80750

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

08/03/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/16/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Product Quest Manufacturing LLC
330 Carswell Ave
Daytona Beach FL United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Sinus Relief (oxymetazoline HCl) Nasal decongestant, 0.05%, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 43236 5.

Product Quantity:

16 bottles

Reason for Recall:

Microbial Contamination of Non-Sterile Products: Failed microbiological testing for Pseudomonas aeruginosa.

Recall Number:

D-0074-2019

Code Information:

Lot: 173089J Exp. 09/19

Class II Drugs Event

Product Description:

DERMATONE (titanium oxide 6% and zinc oxide 4.7%) No-Touch Sunscreen Stick, SPF 50, Net Wt. 0.49 oz. (13.9g) stick, Distributed by: Beaumont Products, Inc. Kennesaw, GA 30144, UPC 0 20908 05100 3.

Product Quantity:

5025 sticks

Reason for Recall:

Microbial Contamination of Non-Sterile Products: sample tested positive for Staphylococcus aureus.

Recall Number:

D-0027-2019

Code Information:

Lot: 172428G

Product Description:

Rhinall (phenylephrine hydrochloride) Nasal Decongestant Nose Drops, 0.25%, 1 FL OZ (30 mL) bottle, Distributed by: Scherer Labs International, LLC., 330 Carswell Ave., Daytona Beach, FL 32117, UPC 3 02747 52531 1.

Product Quantity:

4040 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0028-2019

Code Information:

All lots remaining within expiry.

Product Description:

CareOne, Saline Nasal Gel With Soothing Aloe, Net Wt. 0.5 OZ (14.1 g) tube, Distributed by Foodhold U.S.A., LLC., Landover, MD 20785, 1-877-846-9949, UPC 3 41520 00175 8.

Product Quantity:

4464 tubes

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0029-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Sterile Saline Nasal Mist (sodium chloride) Saline Nasal Moisturizer, 0.9%, packaged in a) Net Wt. 1.52 OZ (43 g) can UPC 0 50428 37079 7 Product #896831; b) Net Wt. 4.25 OZ (120 g) can UPC 0 50428 36124 5; c) Children's Net Wt. 2 OZ (57 g) can UPC 0 50428 58685 3 Product #282472, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895.

Product Quantity:

529,536 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0030-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Saline Nasal Spray, Nasal Moisturizing Spray, Contains: Sodium Chloride 0.65%, Benzyl Alcohol & Benzalkonium Chloride as Preservatives, 1.5 FL OZ (44 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 40814 8 Product #891465.

Product Quantity:

552 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0031-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Sterile Saline Nasal Mist (sodium chloride) Allergy & Sinus Relief, 3.0%, 4.25 OZ (126 g) can, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 41854 3.

Product Quantity:

277,587 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0032-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Baby Nasal Spray/Drops, Non-Medicated, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 29380 5 Product #459367.

Product Quantity:

42,792 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0033-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Saline Nasal Gel with Soothing Aloe, packaged as a) Baby Net Wt. 0.5 OZ (14.2 g) tube UPC 0 50428 58392 0 Product #282476; and b) Net Wt. 0.5 OZ tube (14.2 g) UPC 0 50428 31746 4 Product #896071; Distributed by CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895.

Product Quantity:

285,840 tubes

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0034-2019

Code Information:

All lots remaining within expiry.

Product Description:

CVS Health, Saline Nasal Spray, 1.5 FL OZ bottle, Distributed by CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, Product #277790.

Product Quantity:

552 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0035-2019

Code Information:

All lots remaining within expiry.

Product Description:

Discount Drug Mart, Food Fair, Saline Nasal Spray (sodium chloride) 0.65%, packaged as a) 3 FL OZ (89 mL) bottle UPC 0 93351 01833 6; b) 1.5 FL OZ (45 mL) bottle UPC 0 93351 01834 3, Distributed by: Discount Drug Mart, 211 Commerce Drive, Medina, OH 44256

Product Quantity:

21,492 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0036-2019

Code Information:

All lots remaining within expiry.

Product Description:

DG health, No Drip, Nasal Pump Mist (oxymetazoline hydrochloride), 0.05%, 1 FL OZ (30 mL) bottle, Distributed by: Dolgencorp, LLC, 100 Mission Ridge, Goodlettsville, TN 37072, UPC 7 27510 00373 3 .

Product Quantity:

786,720 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0037-2019

Code Information:

All lots remaining within expiry.

Product Description:

FAMILY wellness, Sterile Saline, Nasal Mist, Saline Nasal Relief (0.9% Sodium Chloride Solution), 4.25 FL OZ (126 mL) can, Distributed by: Midwood Brands, LLC, 10611 Monroe Rd., Matthews, NC 28105, UPC 0 32251 11617 9.

Product Quantity:

46,056 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0038-2019

Code Information:

All lots remaining within expiry.

Product Description:

Harmon Face Values, Saline Nasal Gel with Soothing Aloe, 0.5 oz. (14.1 g) tube, Distributed by: Harmon Stores, Inc., Union, NJ 07083 USA, UPC 7 27510 00474 7 .

Product Quantity:

5040 tubes

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0039-2019

Code Information:

All lots remaining within expiry.

Product Description:

Harmon Face Values, Saline Nasal Spray (sodium chloride), 0.65%, packaged as a) 1.5 FL OZ (44 mL) bottle UPC 7 27510 00501 0; b) 3 FL OZ (88 mL) bottle UPC 7 27510 00502 7, Distributed by Harmon Stores, Inc., Union, NJ 07083 USA.

Product Quantity:

39,924 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0040-2019

Code Information:

All lots remaining within expiry.

Product Description:

meijer, Saline Nasal Spray, Nasal Moisturizing Spray, packaged as a) 1.5 FL OZ (44 mL) UPC 7 08820 74428 8; b) 3FL OZ (88 mL) UPC 7 08820 74430 1, Dist. By Meijer Distribution, Inc., Grand Rapids, MI 49544 .

Product Quantity:

182,568 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0041-2019

Code Information:

All lots remaining within expiry.

Product Description:

Meijer, Sterile Saline Nasal Mist (0.9% Sodium Chloride Solution), 4.25 OZ (120 g) can, Dist. By Meijer Distribution, Inc., 2929 Walker Ave. NW, Grand Rapids, MI 49544, UPC 7 13733 27615 3.

Product Quantity:

37,464 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0042-2019

Code Information:

All lots remaining within expiry.

Product Description:

HuMist Saline Nasal Mist 1.5 FL OZ (45 mL) bottle, Distributed by: Scherer Labs International, LLC. 330 Carswell Ave., Daytona Beach, FL 32117, UPC 3 02742 68045 9 .

Product Quantity:

3264 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0043-2019

Code Information:

All lots remaining within expiry.

Product Description:

Premier Value Nasal Decongestant Extra Moisturizing Nasal Spray (Oxymetazoline HCl 0.05%), 1 FL OZ (30 mL) bottle, Distributed By Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431, NDC 68016-304-03, UPC 8 40986 01518 2.

Product Quantity:

8592 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0044-2019

Code Information:

All lots remaining within expiry.

Product Description:

Premier Value, Nasal Decongestant, No Drip Nasal Spray (oxymetazoline HCl) Nasal Solution, 12 Hour Pump Mist, Maximum Strength, 1 FL OZ (30 mL) bottle, Distributed By Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431, NDC 68016-308-03, UPC 8 40986 01519 9.

Product Quantity:

9024 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0045-2019

Code Information:

All lots remaining within expiry.

Product Description:

Premier Value, Sterile Saline Nasal Mist, Saline Nasal Moisturizer (0.9% Sodium Chloride) Solution, 4.25 FL OZ (126 mL) can, Distributed By Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431, NDC 8 40986 02998 1.

Product Quantity:

10,584 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0046-2019

Code Information:

All lots remaining within expiry.

Product Description:

Premier Value, Nasal Decongestant, Nasal Spray (oxymetazoline HCl 0.05%), Regular Strength, 1 FL OZ (30 mL) bottle, Distributed By Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431, NDC 68016-316-03, UPC 8 40986 01516 8.

Product Quantity:

4992 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0047-2019

Code Information:

All lots remaining within expiry.

Product Description:

Premier Value, Saline Nasal Spray, Sodium Chloride 0.65%, packaged as a) 3 FL OZ (88 mL) bottle NDC 68016-388-00 UPC 8 40986 01483 3; b) 1.5 FL OZ (44 mL) bottle NDC 68016-466-00 UPC 8 40986 01482 6, Distributed By Chain Drug Consortium, 3301 NW Boca Raton Blvd, Suite 101, Boca Raton, FL 33431.

Product Quantity:

102,348 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0048-2019

Code Information:

All lots remaining within expiry.

Product Description:

QC Quality Choice, Saline Nasal Gel with Soothing Aloe, 0.5 OZ (14.1 g) tube, Distributed by C.D.M.A., Inc., 43157 W. Nine Mile, Novi, MI 48376-0995, UPC 6 35515 99202 3.

Product Quantity:

4,200 tubes

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0049-2019

Code Information:

All lots remaining within expiry.

Product Description:

QC Quality Choice, Saline Nasal Relief, Moisturizing Nasal Spray, Sodium Chloride 0.65%, packaged as a) 1.5 FL OZ (45 mL) bottle UPC 6 35515 98845 3; b) 3 FL OZ (89 mL) bottle UPC 6 35515 95042 9, Distributed by C.D.M.A., Inc., 43157 W. Nine Mile, Novi, MI 48376-0995.

Product Quantity:

172,800 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0050-2019

Code Information:

All lots remaining within expiry.

Product Description:

Rite Aid Pharmacy, nasal relief NO DRIP PUMP SPRAY nasal spray, (oxymetazoline hydrochloride 0.05%), 12 Hour, 1 FL OZ (30 mL) bottle, Distributed By: Rite Aid, 30 Hunter Lane, Camp Hill, PA 17011, UPC 0 11822 31412 1.

Product Quantity:

114,336 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0051-2019

Code Information:

All lots remaining within expiry.

Product Description:

Thayers Natural Remedies, Saline Nasal Mist, Allergy & Sinus Relief, Slippery Elm, 3 FL OZ (89 mL) can, Distributed By: Product Quest Manufacturing, LLC, 330 Carswell Ave., Daytona Beach, FL 32117, UPC 7 27510 00659 8.

Product Quantity:

16,944 cans

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0052-2019

Code Information:

All lots remaining within expiry.

Product Description:

Thayers Natural Remedies, Saline Nasal Spray, Allergy & Sinus Relief, Slippery Elm, 1.5 FL OZ (44 mL) bottle, Distributed By: Product Quest Manufacturing, LLC, 330 Carswell Ave., Daytona Beach, FL 32117, UPC 7 27510 00660 4.

Product Quantity:

22,392 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0053-2019

Code Information:

All lots remaining within expiry.

Product Description:

TopCare, Saline Nasal Gel with Soothing Aloe, 0.5 OZ (14 g) tube, Distributed By Topco Associates LLC, Elk Grove Village, IL 60007, UPC 0 36800 42146 2.

Product Quantity:

7,488 tubes

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0054-2019

Code Information:

All lots remaining within expiry.

Product Description:

OCEAN Saline Nasal Spray, packaged in a) 3.5 Fl. Oz. (104 mL) bottle UPC 3 01875 26001 9; b) 45 cc (1.5 fl. oz.) UPC 3 01875 26003 3, c) Buddy Pack containing one 1.5 FL. OZ. (44 mL) and one 0.76 FL.OZ. (22 mL) bottle per carton, Distributed by: Valeant Consumer Products, A Division of Valeant Pharmaceuticals, North America LLC, Bridgewater, NJ 08807.

Product Quantity:

3,442,536 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0055-2019

Code Information:

All lots remaining within expiry.

Product Description:

Best Choice, 12 Hour Extra Moisturizing, Nasal Spray (Oxymetazoline Hydrochloride 0.05%), Nasal Decongestant, 1 FL OZ (30 mL) bottle, Proudly Distributed By: Valu Merchandisers, Co., 5000 Kansas Ave., Kansas City, KS 66106, UPC 0 70038 59328 7.

Product Quantity:

2,112 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0056-2019

Code Information:

All lots remaining within expiry.

Product Description:

Best Choice, 12 Hour Sinus Relief, Nasal Spray (Oxymetazoline Hydrochloride 0.05%) Nasal Decongestant, 1 FL OZ (30 mL) bottle, Proudly Distributed By: Valu Merchandisers, Co., 5000 Kansas Ave, Kansas City, KS 66106, UPC 0 70038 63684 7.

Product Quantity:

1008 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0057-2019

Code Information:

All lots remaining within expiry.

Product Description:

Best Choice, 12 Hour No-Drip Nasal Spray (Oxymetazoline Hydrochloride 0.05%) Nasal Decongestant, 1 FL OZ (30 mL) bottle, Proudly Distributed By: Valu Merchandisers, Co., 5000 Kansas Ave, Kansas City, KS 66106, UPC 0 70038 59895 4.

Product Quantity:

3,600 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0058-2019

Code Information:

All lots remaining within expiry.

Product Description:

Best Choice, SALINE Nasal Spray (Sodium Chloride 0.65% Phenylcarbinol & Benzalkonium Chloride as Preservatives), 1.5 FL OZ (44 mL) bottle, Proudly Distributed By: Valu Merchandisers, Co., 5000 Kansas Ave, Kansas City, KS 66106, UPC 0 70038 58487 2.

Product Quantity:

30,096 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0059-2019

Code Information:

All lots remaining within expiry.

Product Description:

Walgreens, Nasal Spray (Oxymetazoline HCl 0.05%) Nasal Decongestant, Maximum Strength, 12 Hour, 0.75 FL OZ (22 mL) bottle, Distributed By: Walgreen Co., 200 Wilmot Road, Deerfield, IL 60015, UPC 3 11917 18622 1.

Product Quantity:

141,888 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0060-2019

Code Information:

All lots remaining within expiry.

Product Description:

Walgreens, NO DRIP Anefrin Nasal Spray (Oxymetazoline HCl 0.05%), Nasal Decongestant, Extra Moisturizing, 12 Hour, 0.5 FL OZ (15 mL) bottle, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-7004-01, UPC 3 11917 18534 7.

Product Quantity:

286,176 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0061-2019

Code Information:

All lots remaining within expiry.

Product Description:

Well at Walgreens, ULTRA FINE Sinus Relief Mist (Oxymetazoline HCl 0.05%) bottle, Sinus Reliever, Nasal Decongestant, 12 Hour Pump Mist, 0.5 FL OZ (15 mL) bottle, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-7000-01, UPC 3 11917 18535 4.

Product Quantity:

361,104 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0062-2019

Code Information:

All lots remaining within expiry.

Product Description:

Walgreens, NO DRIP, Anefrin Nasal Spray (Oxymetazoline HCl 0.05%), Nasal Decongestant, Original, 12 Hour, Maximum Strength, 0.5 FL OZ (15 mL) bottle, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-7005-01, UPC 3 11917 18537 8.

Product Quantity:

355,056 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0063-2019

Code Information:

All lots remaining within expiry.

Product Description:

Walgreens, NO DRIP Severe Anefrin Nasal Spray (Oxymetazoline HCl 0.05%) Nasal Decongestant, Maximum Strength, 12 Hour + Menthol, 0.5 FL OZ (15 mL) bottle, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-7001-01, UPC 3 11917 18536 1.

Product Quantity:

533,016 bottles

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0064-2019

Code Information:

All lots remaining within expiry.

Product Description:

dr. brandt, BB cream with signature FLEXITONE, SPF 30, 1 oz./30 g tube, Distributed by: Cosmetic Dermatology, Inc., Miami, FL 33172, UPC 6 63963 00828 7.

Product Quantity:

9,480 tubes

Reason for Recall:

Failed Stability Specifications: separation of product and failure for actives.

Recall Number:

D-0065-2019

Code Information:

Lot: 161223D, Exp. 4/16/2019

Product Description:

FREEZE IT (camphor 0.2% and menthol 3.5%) spray, 118.29 mL (4 fl. oz.) can, Distributed by: Expedite Products, Inc., Tampa, FL 33619 USA, UPC 8 56569 00203 6.

Product Quantity:

6,109 cans

Reason for Recall:

Superpotent Drug: high out of specification assay results for the camphor ingredient.

Recall Number:

D-0066-2019

Code Information:

Lot: 170498B, Exp. 02/23/2020

Product Description:

Rite Aid Pharmacy, First Aid Antibiotic Ointment, (neomycin sulfate 3.5 mg, polymyxin B sulfate 5,000 units, bacitracin zinc 400 units per gram), 2 OZ (56 g) tube, Distributed By: Rite Aid, 30 Hunter Lane, Camp Hill, PA 17011, UPC 0 11822 55441 1.

Product Quantity:

5,004 tubes

Reason for Recall:

Subpotent Drug: low out of specification assay results for the bacitracin zinc ingredient.

Recall Number:

D-0067-2019

Code Information:

Lot: 170591E, Exp. 11/17/18

Product Description:

Premier Value, Fast Relief, Muscle Rub, (menthol 10% and methyl salicylate 15%) 4 OZ (113 g) tube, Distributed By: Chain Drug Consortium, 3301 NW Boca Raton Blvd., Suite 101, Boca Raton, FL, 33431, UPC 8 40986 01341

Product Quantity:

4,692 tubes

Reason for Recall:

Superpotent Drug: high out of specification assay results for the menthol ingredient.

Recall Number:

D-0068-2019

Code Information:

Lot. 172598G, Exp. 7/4/2019

Product Description:

CeraVe Healing Lip Balm/SPF 30 (avobenzone 3%, dimethicone 1%, homosalate 10%, octisalate 5%, octocrylene 10%, Net Wt. 0.15 oz. (4.25 g) stick, CeraVe LLC., New York, NY 10001, UPC 3 01872 49201 7.

Product Quantity:

25,596 sticks

Reason for Recall:

Microbial Contamination of Non-Sterile Products: Failed microbiological testing for Staphalococcus aureus.

Recall Number:

D-0071-2019

Code Information:

Lot: PSP85W/172792H

Product Description:

Mushatt's No. 9, PsoriWash Medicated Wash, Salicylic Acid 1.8%, 8 oz. (226 g) tube, Distributed by Mushatts, LLC, P.O. Box 372476, Satellite Beach, FL 32937, UPC 8 58245 00203 3.

Product Quantity:

1,440 tubes

Reason for Recall:

Microbial Contamination of Non-Sterile Products and Subpotent Drug: failure for microbiological growth exceeding specification and low out of specification assay results for salicylic acid.

Recall Number:

D-0072-2019

Code Information:

Lot: 161794F

Product Description:

CVS Health, Original Strength, Triple Antibiotic Ointment Spray (bacitracin zinc 400 units, neomycin sulfate 3.5 mg, polymyxin B sulfate 5,000 units per gram), 2 OZ (57 g) can, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, Product#957603, UPC 0 50428 29525 0.

Product Quantity:

11,016 cans

Reason for Recall:

Subpotent Drug: low out of specification assay results for the bacitracin zinc ingredient.

Recall Number:

D-0073-2019

Code Information:

Lot: 170591E, Exp. 11/17/18

Product Description:

Rhinall Nasal Decongestant Nasal Spray (phenylephrine HCl), 0.25%, 1 1/3 Fl Oz. (40 ml), Manufactured for: Scherer Laboratories, Inc., Atlanta, GA 30339.

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0075-2019

Code Information:

All lots remaining within expiry.

Product Description:

Rexall, Sinus Nasal Pump Mist, (Oxymetazoline Hydrochloride 0.05%), 1 FL OZ (30mL) bottle, SKU 00744201

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0076-2019

Code Information:

All lots remaining within expiry.

Product Description:

Rexall, Extra Moisturizing No Drip Nasal Spray (Oxymetazoline Hydrochloride 0.05%) 1 FL OZ (30 mL) bottle, 48/3/1 #12687901 w/ Silo

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0077-2019

Code Information:

All lots remaining within expiry.

Product Description:

Rexall, Extra Moisturizing No Drip Nasal Spray (Oxymetazoline Hydrochloride 0.05%) 1 FL OZ (30 mL) bottle, 48 pk. (12687901)

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0078-2019

Code Information:

All lots remaining within expiry.

Product Description:

Finafta Baby, Oral Gel (benzocaine 7.5%), 7.1 Grams (0.25 Oz.) tube, Distributed By: Efficient Laboratories, Inc., Miami, FL 33166.

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0079-2019

Code Information:

All lots remaining within expiry.

Product Description:

Family Dollar Saline Nasal Spray 4.25 oz. can, 24 pk, SKU 0900562.

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: products manufactured under conditions that could impact its product quality.

Recall Number:

D-0080-2019

Code Information:

All lots remaining within expiry.

Class II Drugs Event

Event ID:

81061

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

08/28/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/12/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Humco Holding Group, Inc
7400 Alumax Rd
Texarkana TX United States

Distribution Pattern:

Nationwide.

Associated Products**Product Description:**

Thyroid, USP (Porcine) Levothyroxine 36.3 mcg/grain Liothyronine 9.7 mcg/grain Active Pharmaceutical Ingredient Rx Only 1000 grams NDC 0395-8077-43 Packaged by: Humco Texarkana, TX 75501

Product Quantity:

Unknown

Reason for Recall:

CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:

D-0022-2019

Code Information:

Lots: A24542 Exp. 02/2019; A25528 Exp. 04/2019; A27119 Exp. 05/2019; A27810 Exp. 06/2019

Product Description:

Thyroid, USP (Porcine) Levothyroxine 36.3 mcg/grain Liothyronine 9.7 mcg/grain Active Pharmaceutical Ingredient Rx Only 100 grams NDC 0395-8077-62 Packaged by: Humco Texarkana, TX 75501 USA

Product Quantity:

Unknown.

Reason for Recall:

CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:

D-0023-2019

Code Information:

Lots: A24543 Exp. 02/2019; A25724 Exp. 01/2019; A25529 Exp. 04/2019; A25723 Exp. 04/2019; A27120 Exp. 05/2019; A27811 Exp. 06/2019; A28626 Exp. 06/2019; A29171 Exp. 06/2019; A29221 Exp. 06/2019

Product Description:

Thyroid, USP (Full Strength) Levothyroxine 112.1 mcg/grain Liothyronine 29.2 mcg/grain Active Pharmaceutical Ingredient Rx Only 1000 grams NDC 0395-6580-43 Packaged by: Humco Texarkana, TX 75501 USA

Product Quantity:

10 kilograms

Reason for Recall:

CGMP Deviations: Recall notice received from supplier that Thyroid Powder has inconsistent levels of the active ingredients levothyroxine and liothyronine.

Recall Number:

D-0024-2019

Code Information:

Lot: A26450 Exp. 05/2019

Class II Drugs Event

Event ID:

81069

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/20/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/18/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:

Product was distributed throughout the United States to various distributors who may have further distributed the product.

Associated Products

Product Description:

Clonazepam Orally Disintegrating Tablets USP, 2 mg., 60-count carton. RX only. Teva Pharmaceuticals USA, INC. North Wales, PA 19454. NDC 0555-0098-96

Product Quantity:

1,373 60-count cartons

Reason for Recall:

Failed Stability Specifications: Out-of-specification test result for water content obtained during routine stability testing.

Recall Number:

D-0082-2019

Code Information:

Lot # 34033752A, EXP 1/2020

Class III Drugs Event

Event ID:

80750

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/03/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/16/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Product Quest Manufacturing LLC
330 Carswell Ave
Daytona Beach FL United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Well at Walgreens, Scar Cream with SPF 30, (Avobenzone 3%, Octocrylene 10%, Oxybenzone 6%), 0.7 OZ (19.8 g) tube, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, UPC 3 11917 18281 0.

Product Quantity:

6,516 tubes

Reason for Recall:

Subpotent Drug: low out of specification assay results for the octocrylene and avobenzone ingredients.

Recall Number:

D-0069-2019

Code Information:

Lot: 163241K, Exp. October 2018

Product Description:

Cicatricure, Scar Cream + Sunscreen SPF 30 (avobenzone 3%, octocrylene 10%, oxybenzone 6%), 0.7 oz. (19.8 g) tube, Distributed by: Genomma Lab USA Inc., Houston, TX 77027, UPC 6 50067 00018 7.

Product Quantity:

7,944 tubes

Reason for Recall:

Subpotent Drug: low out of specification assay results for the octocrylene and avobenzone ingredients.

Recall Number:

D-0070-2019

Code Information:

Lot: 163241K, Exp. October 2018

Class III Drugs Event

Event ID:

81221

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/27/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/14/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:

Product was distributed throughout the United States.

Associated Products

Product Description:

Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.03 mg, Rx Only, 3 extended-cycle blister packs containing 91 tablets each, Made in India, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., NDC 0378-7281-53.

Product Quantity:

5,790 cartons (526,890 tablets)

Reason for Recall:

Labeling: Not Elsewhere Classified-Incorrect NDC and product name identified on blister packs.

Recall Number:

D-0025-2019

Code Information:

Lot # 8508F004A; Exp. 02/20

Not Yet Classified Drugs Event

10/24/2018

Print View

Event ID:

81189

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

10/05/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amerigen Pharmaceuticals Inc.
9 Polito Ave Ste 900
Lyndhurst NJ United States

Distribution Pattern:

Product was distributed U.S. nationwide.

Associated Products

Product Description:

Temozolomide capsules, 20 mg, packaged in a) 5-count (NCD 43975-253-05), b) 14-count bottle (NDC 43975-253-14), Rx only, Mfd. by: Stason Pharmaceuticals, Inc., Irvine, CA 92618, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ 07071.

Product Quantity:

5,232 bottles: a) 4,146 bottles; b) 1,086 bottles

Reason for Recall:

Failed dissolution specifications: Out-of-Specification dissolution results obtained during stability testing.

Recall Number:

Code Information:

Lot #: a) 17F058A, Exp 6/19; b) 17F058B, Exp 6/19