

Enforcement Report - Week of July 28, 2021

Class I Drugs Event

Event ID:
87624

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/16/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Ummzy, LLC
273 5th St Unit A
Palisades Park NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:

Krazy Night capsule, packaged in a) 1-count per blister card and b) 10-count boxes, Manufactured by: SUM MARKETING LLC, Made in USA
UPC 746695241860

Product Quantity:

Reason for Recall:

Marketed Without An Approved NDA/ANDA: Products found to contain undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0662-2021

Code Information:

All lots within expiry.

Product Description:

Shogun-X capsules, 10-count boxes, Manufactured by Power Life Distributors, Made in USA, UPC 118122030185

Product Quantity:

364 boxes/10 capsules per box

Reason for Recall:

Marketed Without An Approved NDA/ANDA: Products found to contain undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0663-2021

Code Information:

All lots within expiry.

Product Description:

Thumbs up 7 Red 70K capsules, 10-count boxes, Distributed Ummzy LLC, Made in USA, UPC 617135894680.

Product Quantity:

163 boxes/10 capsules per box

Reason for Recall:

Marketed Without An Approved NDA/ANDA: Products found to contain undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0664-2021

Code Information:

All lots within expiry.

Class I Drugs Event

Event ID:

87641

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

03/29/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/19/2021

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Nuri Trading LLC
800 Palisade Ave
Fort Lee NJ United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Shogun-X 7000 capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC

Product Quantity:
Reason for Recall:

Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil and sildenafil, two FDA approved drugs making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0685-2021

Code Information:

all lots within expiry

Product Description:

Thumbs Up 7 Black 25K capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC

Product Quantity:
Reason for Recall:

Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil, an FDA approved drug making this an unapproved drug for which the safety and efficacy has not been established and therefore subject to recall.

Recall Number:

D-0686-2021

Code Information:

all lots within expiry

Product Description:

Thumbs Up 7 White 11K capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC

Product Quantity:
Reason for Recall:

Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil sildenafil, and vardenafil, FDA approved drugs making them an unapproved drug for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0687-2021

Code Information:

all lots within expiry

Product Description:

69MODE Blue 69 capsule, packaged in 10-count box, Nuri Trading LLC

Product Quantity:
Reason for Recall:

Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil and sildenafil, two FDA approved drugs

making it an unapproved drug for which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-0688-2021

Code Information:

all lots within expiry

Class I Drugs Event

Event ID:

87828

Status:

Ongoing

Recall Initiation Date:

04/27/2021

Center Classification Date:

07/19/2021

Recalling Firm:

Scentsational Soaps & Candles Inc
730 Commerce Dr
Venice FL United States

Distribution Pattern:

USA Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

Ulta beauty Fresh Lemon Citron Frais, 70% Alcohol Hand Sanitizer Spray, Net Wt. 100.55/3.4 fl. oz., UPC 717897092017

Product Quantity:

12,976 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0666-2021

Code Information:

Lots #: 20357A, 20358B, 20363C, Exp 12/1/2022

Product Description:

SS Coconut Breeze Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL), a) Black and White Collection; b) Photo Real Collection

Product Quantity:

a) 2,952 bottles; b) 2,988 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0667-2021

Code Information:

Lot #: 20252

Product Description:

SS Eucalyptus Mint Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL), a) Black and White Collection; b) Photo Real Collection

Product Quantity:

a) 4,248 bottles; b) 3,960 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0668-2021

Code Information:

Lot #: 20248

Product Description:

SS Lavender & Herbs Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL) a) Black and White Collection; b) Photo Real Collection

Product Quantity:

a) 5,112 bottles; b) 4,968 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0669-2021

Code Information:

Lots #: a) 20253, b) 20252

Product Description:

SS Lemon Zest Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL) a) Black and White Collection; b) Photo Real Collection

Product Quantity:

a) 4,680 bottles; b) 4,968 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0670-2021

Code Information:

Lot #: 20255

Product Description:

SS Tangerine & Guava Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL) a) Black and White Collection; b) Photo Real Collection

Product Quantity:

a) 4,788 bottles; b) 3,168 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0671-2021

Code Information:

Lot #: 20254

Product Description:

Goose Creek Hand Sanitizer aloe Blueberry Limeade, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek
www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 14630 02049 5

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0672-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Limoncello, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498
S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 18489 01333 2

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0673-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Beach Dreams, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandles.com, 1498 S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 18489 01336 3

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0674-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Grape Soda, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01328 8

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0675-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Champagne Bubbles, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01334 9

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0676-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Dragonfruit Splash, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01332 5

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0677-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Marshmallows, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01331 8

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0678-2021

Code Information:

Lot #: 20258

Product Description:

Goose Creek Hand Sanitizer aloe Melon Picnic, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02424 0

Product Quantity:

1,260 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0679-2021

Code Information:

Lot #: 20259

Product Description:

Goose Creek Hand Sanitizer aloe Optimistic Vibes, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02234 5

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0680-2021

Code Information:

Lot #: 20259

Product Description:

Goose Creek Hand Sanitizer aloe Red, White & Blue Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02045 7

Product Quantity:

1,512 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0681-2021

Code Information:

Lot #: 20259

Product Description:

Goose Creek Hand Sanitizer aloe Watermelon Lemonade, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 814630 02423 3

Product Quantity:

1,296 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0682-2021

Code Information:

Lot #: 20259

Product Description:

Goose Creek Hand Sanitizer aloe Tropical Daydream, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01335 6

Product Quantity:

1,260 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0683-2021

Code Information:

Lot #: 20260

Product Description:Coconut Stand CoCo TKO Hand Sanitizer, Totally Knocks Out 99.9% of Germs, 3.4 FL. OZ. (100.55 mL), Distributed by: Beauty Sparks LLC
St. Petersburg, FL 33711**Product Quantity:**

500 bottles

Reason for Recall:

Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.

Recall Number:

D-0684-2021

Code Information:

Lot #: 20260

Class II Drugs Event

Event ID:

88159

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

07/09/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/20/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:Innoveix Pharmaceuticals Inc
3790 Arapaho Rd
Addison TX United States**Distribution Pattern:**

Nationwide within the United States

Associated Products

Product Description:Compounded Lyophilized Semorelin/Ipamorelin 3 mg For subcutaneous or intramuscular injection, Rx Only, Compounded by: Innoveix
Addison, TX 75001 800-370-1910**Product Quantity:**

728 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0692-2021

Code Information:

Lot #: SIP215 Exp. 01/14/2022, SIP220 Exp. 01/23/2022, SIP210 Exp. 12/15/2021

Product Description:Compounded Lyophilized AOD-9604, 3 mg For subcutaneous or intramuscular injection, Rx Only, Compounded by: Innoveix Addison, TX
75001 800-370-1910**Product Quantity:**

1,316 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0693-2021

Code Information:

Lot #: AOD205 Exp. 11/09/2021; AOD210 Exp. 11/18/2021; AOD215 Exp. 12/15/2021; AOD220 Exp. 01/20/2022.

Class III Drugs Event

Event ID:

88145

Status:

Ongoing

Recall Initiation Date:

06/22/2021

Center Classification Date:

07/19/2021

Recalling Firm:Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States**Distribution Pattern:**

Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Erythromycin Topical Solution USP, 2% 60 mL, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310, NDC 52565-027-59

Product Quantity:

7872 tubes

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0689-2021

Code Information:

Lot 14180

Product Description:

Erythromycin Topical Gel, 2%, Net Wt. (a) 30 g,(NDC 52565-033-30) (b) 60 g,(NDC 52565-033-60) Rx Only, Manufactured by: Teligent Pharma, Inc. , Buena, NJ 08310,

Product Quantity:

22,824 tubes

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0690-2021

Code Information:

1) NDC 52565-033-30 Lot 14010, Exp July 2021; 2) NDC 52565-033-60 Lot 13865, Exp June 2021; Lot 14011, Exp July 2021.

Class III Drugs Event

Event ID:

88244

Status:

Ongoing

Product Type:

Drugs

Date Terminated:

Recall Initiation Date:

07/07/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

07/16/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

LNK International, Inc.
55 Arkay Dr
Hauppauge NY United States

Distribution Pattern:

Distributed in PA

Associated Products

Product Description:

Acetaminophen EXTRA STRENGTH Pain Reliever / Fever Reducer, Enteric Coated, 50 Coated Tablets/ 500 mg each, Distributed by Amerisource Bergen, 1300 Morris Drive, Chesterbrook, PA, 19087, NDC 46122-649-71

Product Quantity:

8,472 bottles

Reason for Recall:

Labeling: Not Elsewhere Classified The primary label contains the words "enteric coated" but the tablet is not enteric coated and should only say 'coated tablet'

Recall Number:

D-0665-2021

Code Information:

Lot # P120999, Exp 07/31/2022