# Enforcement Report - Week of July 21, 2021

## Class I Drugs Event

**Event ID:**
87511

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/10/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/13/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Sanit Technologies, LLC dba Durisan
7810 25th Ct E Unit 106
Sarasota FL United States

**Distribution Pattern:**
Nationwide in the USA and Bahamas

## Associated Products

**Product Description:**
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizer, listed as 0.1% or 0.13%, Alcohol-Free, packaged in a) 18 mL Net Content 0.61 fl oz credit card size container, (UPC 8 52379 00614 1); b) 50 mL Net Content 1.69 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 7); c) 118 mL Net Content 4 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 9); d) 236.58 mL Net Content 8 oz bottle, (UPC 8 52379 00635 6); e) 250 mL Net Contents 8.45 oz (UPC 8 52379 00611 0); f) 300 mL Net Content 10 oz bottle, (UPC 8 52379 00697 4); g) 550 mL Net Content 18.59 oz bottle, (UPC 8 52379 00620 2) ; h) 1000 mL Net Content 33.81 oz kidney bottle dispensing 0.4 or 0.8 each actuation, (UPC 8 50008 48507 7 and 8 52379 00610 3); and i) 1 Gallon Net Content 128 oz bottle, (UPC 8 52379 00621 9); Sanit Technologies, LLC 7810 25th Court East, Unit 106 Sarasota, Florida 34243

**Product Quantity:**
8,609,863 credit card size containers, 665,395 bottles, and 70,462 kidney bottles TOTAL

**Reason for Recall:**
Microbial Contamination of Non-Sterile Products: firm's internal testing found certain lots of the product to be contaminated with Burkholderia contaminans and/or yeast and mold.

**Recall Number:**
D-0656-2021

**Code Information:**
Lots: DHS030920A1-A, DHS030920A2-S, DHS030920A3-S, Exp. 4/9/2022; DHS031020A4-S, DHS031020A5-S, DHS031020A6-S, DHS031020A7-S, DHS031020A8-S, Exp. 4/10/2022; DHS031120A1-S, DHS031120A2-S, DHS031120A3-S, DHS031120A4-S, DHS031120A5-S, DHS031120A6-S, Exp.4/11/2022; DHS051420A1-S, Exp. 6/14/2022; DHS052020A1-S, DHS052020B1-S, DHS052020C1-S, Exp. 6/20/2022; DHS052220B1-S, Exp. 6/22/2022; DHS052620B1-S, Exp. 6/26/2022; DHS052720C1-S, DHS052720D1-S, Exp. 6/27/2022, DHS052820B1-S, DHS052820C1-S, DHS052820D1-S, Exp. 6/28/2022; DHS060120A1-S, Exp. 7/1/2022; DHS060220A1-S, DHS062220C-S, Exp. 7/22/2022

**Product Description:**
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizing Wipes, 0.13%, 160-count canister; Sanit Technologies, LLC, 7810 25th Court East, Sarasota, Florida 34243, UPC 8 52379 00631 8.

**Product Quantity:**
42,905 canisters TOTAL

**Reason for Recall:**
Microbial Contamination of Non-Sterile Products: firm's internal testing found certain lots of the product to be contaminated with Burkholderia contaminans and/or yeast and mold.

**Recall Number:**
D-0657-2021

**Code Information:**
Lots: DHS031020A4-S, DHS031020A6-S, Exp. 4/10/2022

## Class I Drugs Event

**Event ID:**
87918

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/11/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/12/2021

**Initial Firm Notification of Consignee or Public:**
Press Release

**Recalling Firm:**
Yamtun7
955 Egret Cir
Delray Beach FL United States

**Distribution Pattern:**
Unknown; unable to determine due to firm's Ebay account being closed.

## Associated Products

**Product Description:**
Poseidon Platinum 3500 capsule, 1-count per blister card, Distributed by: Poseidon, Made in the USA, UPC 0 95842 05876 0

**Product Quantity:**
36 capsules

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

**Recall Number:**
D-0654-2021

**Code Information:**
All lots distributed 07/01/2019 through 09/28/2020.

## Class I Drugs Event

**Event ID:**
88190

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/22/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/20/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Ardil Comercial S.R.L.
Pastora Elida Km 19 No. 03, Apto. 1
Santo Domingo Este Dominican Republic (the)

**Distribution Pattern:**
Product was distributed to one client in NYC who further distributed the product.

## Associated Products

**Product Description:**
Limar Hand Sanitizer, Isopropyl Alcohol 70%, Cont. 4 oz bottles, Manufactured in Dominican Republic: by Ardil Comercial S.R.L., Santo Domingo, Dominican Republic UPC 7 487040 301587

**Product Quantity:**
1,260 bottles

**Reason for Recall:**
Labeling Not Elsewhere Classified: Hand sanitizer packaged in containers resembling drinking water bottles.

**Recall Number:**
D-0691-2021

**Code Information:**
Batch Number # 079932-4611-05-J, exp. date May 2022

## Class II Drugs Event

**Event ID:**
87511

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/10/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/13/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Sanit Technologies, LLC dba Durisan
7810 25th Ct E Unit 106
Sarasota FL United States

**Distribution Pattern:**
Nationwide in the USA and Bahamas

## Associated Products

**Product Description:**
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizer, listed as 0.1% or 0.13%, Alcohol-Free, packaged in a) 18 mL Net Content 0.61 fl oz credit card size container, (UPC 8 52379 00614 1); b) 50 mL Net Content 1.69 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 7); c) 118 mL Net Content 4 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 9); d) 236.58 mL Net Content 8 oz bottle, (UPC 8 52379 00635 6); e) 250 mL Net Contents 8.45 oz (UPC 8 52379 00611 0); f) 300 mL Net Content 10 oz bottle, (UPC 8 52379 00697 4); g) 550 mL Net Content 18.59 oz bottle, (UPC 8 52379 00620 2) ; h) 1000 mL Net Content 33.81 oz kidney bottle dispensing 0.4 or 0.8 each actuation, (UPC 8 50008 48507 7 and 8 52379 00610 3); and i) 1 Gallon Net Content 128 oz bottle, (UPC 8 52379 00621 9); Sanit Technologies, LLC 7810 25th Court East, Unit 106 Sarasota, Florida 34243

**Product Quantity:**
8,609,863 credit card size containers, 665,395 bottles, and 70,462 kidney bottles TOTAL

**Reason for Recall:**
CGMP Deviations: lots recalled due to CGMP deviations because they were manufactured under the same conditions as product lots found to be contaminated.

**Recall Number:**
D-0658-2021

**Code Information:**
Lots: DHS041519A1-S, DHS041519A2-S, DHS041519A3-S, DHS041519A4-S, DHS041519A5-S, DHS041519A6-S, Exp. 5/15/2021; DHS042919AR1-S, Exp. 5/29/2021; DHS043019AR1-S, Exp. 5/30/2021; DHS050319A4-S, Exp. 6/03/2021; DHS053019A1-S, DHS053019A2-S, DHS053019A4-S, DHS053019A5-S, DHS053019A6-S, Exp. 6/30/2021; DHS070219A1-S, DHS070219A2-S, DHS070219A3-S, DHS070219A4-S, DHS070219A5-S, DHS070219A6-S, DHS070219AB-S, Exp. 8/2/2021; DHS080219A1-S, Exp. 9/2/2021; DHS091819A1-S, Exp 10/18/2021; DHS032820B1-S, Exp 4/28/2022; DHS051520A1R1-S, Exp. 6/15/2022; DHS052020A1R1-S, DHS052020B1R1-S, DHS052020CR1-S, Exp. 6/20/2022; DHS052220A1R1-S, Exp. 6/22/2022; DHS052720C1R1-S, Exp 6/27/2022; DHS052920A1R1-S, DHS052920B1R1-S, DHS052920C1R1-S, Exp 6/29/2022; DHS060320C1R1-S, Exp. 7/3/2022; DHS060520C1R1-S, DHS060520F1R1-S, Exp. 7/5/2022; DHS060820E1R1-S, Exp. 7/8/2022; DHS061220A1R1-S, Exp. 7/12/2022; DHS061920B1R1-S, Exp. 7/19/2022; DHS062320B1R1-S, Exp. 7/23/2022; DHS062420B1R1-S, Exp. 7/24/2022; DHS081120A1-S, Exp. 9/11/2022; DHS081220A1R1-S, Exp 9/12/2022; DHS081420B1-S, DHS081420B3-S, DHS081420B6-S, DHS081420B8-S, Exp. 9/14/2022; DHS081720A3-S, DHS081720A5-S, Exp. 9/17/2022

**Product Description:**
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizing Wipes, 0.13%, packaged in 80-count canister (UPC 8 52379 00632 5), b) 160-count canister (UPC 8 52379 00631 8), and c) 240-count canister (UPC 8 52379 00633 2); Sanit Technologies, LLC, 7810 25th Court East, Sarasota, Florida 34243.

**Product Quantity:**
43,164 canisters TOTAL

**Reason for Recall:**
CGMP Deviations: lots recalled due to CGMP deviations because they were manufactured under the same conditions as product lots found to be contaminated.

**Recall Number:**
D-0659-2021

**Code Information:**
DHS041519A1-S, DHS041519A2-S, DHS041519A3-S, DHS041519A4-S, DHS041519A5-S, DHS041519A6-S, Exp. 5/15/2021; DHS042919AR1-S, Exp. 5/29/2021; DHS043019AR1-S, Exp. 5/30/2021; DHS050319A4-S, Exp. 6/03/2021; DHS053019A1-S, DHS053019A2-S, DHS053019A4-S, DHS053019A5-S, DHS053019A6-S, Exp. 6/30/2021; DHS070219A1-S, DHS070219A2-S, DHS070219A3-S, DHS070219A4-S, DHS070219A5-S, DHS070219A6-S, DHS070219AB-S, Exp. 8/2/2021; DHS080219A1-S, Exp. 9/2/2021; DHS091819A1-S, Exp 10/18/2021; DHS032820B1-S, Exp 4/28/2022; DHS051520A1R1-S, Exp. 6/15/2022; DHS052020A1R1-S, DHS052020B1R1-S, DHS052020CR1-S, Exp. 6/20/2022; DHS052220A1R1-S, Exp. 6/22/2022; DHS052720C1R1-S, Exp 6/27/2022; DHS052920A1R1-S, DHS052920B1R1-S, DHS052920C1R1-S, Exp 6/29/2022; DHS060320C1R1-S, Exp. 7/3/2022; DHS060520C1R1-S, DHS060520F1R1-S, Exp. 7/5/2022; DHS060820E1R1-S, Exp. 7/8/2022; DHS061220A1R1-S, Exp. 7/12/2022; DHS061920B1R1-S, Exp. 7/19/2022; DHS062320B1R1-S, Exp. 7/23/2022; DHS062420B1R1-S, Exp. 7/24/2022; DHS081120A1-S, Exp. 9/11/2022; DHS081220A1R1-S, Exp 9/12/2022; DHS081420B1-S, DHS081420B3-S, DHS081420B6-S, DHS081420B8-S, Exp. 9/14/2022; DHS081720A3-S, DHS081720A5-S, Exp. 9/17/2022

## Class II Drugs Event

**Event ID:**
88090

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/10/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/15/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
CIPLA
10 Independence Blvd
Warren NJ United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Solifenacin Succinate Tablets, 10 mg, 30-count bottles, Rx Only, Manufactured by: Cipla Ltd., Verna, Goa, India Manufactured for Cipla USA, Inc. 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL, 33323, NDC 69097-261-02.

**Product Quantity:**
7228 bottles

**Reason for Recall:**
CGMP Deviations

**Recall Number:**
D-0660-2021

**Code Information:**
Lot #: GG90819, Exp. Date 06/2021

## Class II Drugs Event

**Event ID:**
88224

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
07/02/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/09/2021

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
The Harvard Drug Group

17187 N Laurel Park Dr Ste 300
Livonia MI United States

**Distribution Pattern:**
Distributed in OH and NJ

## Associated Products

**Product Description:**
NIFEdipine EXTENDED-RELEASE TABLETS, USP 30 mg Rx only packaged as a) 100 count unit dose carton, NDC 0904-7080-61; b) 50 count unit dose carton, NDC 0904-7080-06: Distributed by: Ingenus Pharmaceuticals, LLC Orlando, FL 32839-6408 Distributed by: Major Pharmaceuticals 17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152 USA

**Product Quantity:**
504 Cartons of 50 count each; 372 Cartons of 100 count each

**Reason for Recall:**
Failed Dissolution Specification: Out of specification for dissolution during routine stability testing.

**Recall Number:**
D-0652-2021

**Code Information:**
Lots: a)N00418 Exp. 09/2022, b) N00417 Exp. 09/2022

## Class III Drugs Event

**Event ID:**
88164

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/23/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
07/13/2021

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Partner Therapeutics Inc
2625 162nd St Sw
Lynnwood WA United States

**Distribution Pattern:**
Product was distributed to one government account (ASPR)

## Associated Products

**Product Description:**
LEUKINE (Sargramostim) for Injection, 250 mcg/ vial, 5mL vials, 5 (250 mcg vials) per box, Rx only, Mfd by Partner Therapeutics, Inc. Lexington, MA 02421, NDC 71837-5843-5

**Product Quantity:**
32,260 vials

**Reason for Recall:**
FAILED STABILITY SPECIFICATION: Out-of-specification (OOS) result observed for Leukine (sargramostim) at the 27-month stability timepoint.

**Recall Number:**
D-0655-2021

**Code Information:**
Lot #: E8023E, exp. date 11/30/2022

## Class III Drugs Event

**Event ID:**
88182

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/18/2021

**Center Classification Date:**
07/12/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

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

**Recalling Firm:**
Grato Holdings, Inc.
201 Apple Blvd
Woodbine IA United States

**Distribution Pattern:**
FL

## Associated Products

**Product Description:**
B-Force, Homeopathic, 1 Fl Oz (30 mL) bottle, Distributed by: BioActive Nutritional, Inc., Melbourne, FL 32935, NDC 43857-0576-1

**Product Quantity:**
1480 bottles

**Reason for Recall:**
Superpotent

**Recall Number:**
D-0653-2021

**Code Information:**
Lot: Z61917

## Not Yet Classified Drugs Event

**Event ID:**
88156

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
06/21/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**

**Initial Firm Notification of Consignee or Public:**
Press Release

**Recalling Firm:**
Prairie Wolf Spirits
124 E Oklahoma Ave
Guthrie OK United States

**Distribution Pattern:**
Nationwide in the US

## Associated Products

**Product Description:**
Prairie Wolf Distillery Alcohol Antiseptic 80%, Topical Solution Hand Sanitizer, packaged in a) (16.9oz) 500 mL (UPC 8 60003 31899 7, NDC: 73891-100-14); and b) (20oz) 591 mL (UPC 8 60003 65984 7 NDC: 73891-100-15) bottles, Prairie Wolf Distillery, Guthrie, Oklahoma

**Product Quantity:**
Unknown

**Reason for Recall:**
Hand sanitizer packaged in bottles that resemble beverage containers.

**Recall Number:**

**Code Information:**
All lots