Enforcement Report - Week of July 7, 2021

Class I Drugs Event

Event ID:
87712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/28/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
NSNY Distributor Inc
4570 192nd St
Flushing NY United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Premium OrgaZEN 7000 capsule, 1-count per blister card, distributed by: Nutra Vita Co, Santa Fe Springs, CA, Made in USA , UPC 0 40232 32555 7

Product Quantity:
2600 capsules

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/ or tadalafil

Recall Number:
D-0641-2021

Code Information:
all lots

Product Description:
Ginseng Power 5000 capsule, 1- count per blister card, GS Natural Co, Los Angeles, CA 90010, UPC 0 40232 18144 3

Product Quantity:
399 capsules

Reason for Recall:
Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/ or tadalafil

Recall Number:
D-0642-2021

Code Information:
all lots

Class I Drugs Event

Event ID:
87917

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
DIBAR NUTRICIONAL S DE RL DE CV
Sargento Manuel De La Rosa #145 Col Chapultepec Sur
Morelia Mexico

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
DiBAR LABS Hand Sanitizer (ethyl alcohol 70%), 8 FL OZ. (236.5 mL), Distributed by S.E.N.D. LLC, Anthony, NM 88021, Imported by Dibar Labs, LLC, Sugar Land, TX 77479, Made in Mexico,77479, NDC 73009-0001-08 UPC 8 53090 00301 3.

Product Quantity:
Unknown quantity

Reason for Recall:
Chemical Contamination: FDA analysis found 3 lots of DiBAR hand Sanitizer to be below the label claim for ethanol content and to contain methanol.

Recall Number:
D-0644-2021

Code Information:
Lot # LDHSN050920 T1, LDHSN051020 DESC, LDHSN051020 T2, EXP 05/2022

Class II Drugs Event

Product Description:
DiBAR LABS Hand Sanitizer, (ethyl alcohol 70%), packaged as a) 16 FL OZ (473.1 mL) bottle, NDC 73009-001-16, UPC 8 53090 00302 0 and b) 8 FL OZ (236.5 mL) bottle, NDC 73009-0001-08, UPC 8 53090 00301 3; Distributed by: S.E.N.D, LLC., Anthony, NM 88021; Imported by: Dibar Labs, LLC., Sugar Land, TX 77479, Made in Mexico.

Product Quantity:
Unknown quantity

Reason for Recall:
CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.

Recall Number:
D-0645-2021

Code Information:
All lots

Product Description:
ProtectoRx (ethyl alcohol 70%), packaged in a) 2 FL OZ (59 mL), NDC 75408-002-01 and b) 16 FL OZ (473.2 mL), NDC 75408-002-02 bottles, Imported by: Dibar Labs, LLC., Sugar Land, TX 77479; Distributed by: PR Trading LLC, PO Box 19647, San Juan, PR 00910, Made in Mexico.

Product Quantity:
Unknown quantity

Reason for Recall:
CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.

Recall Number:
D-0646-2021

Code Information:
All lots.

Product Description:
ADVANCE HAND SANITIZER, (ethyl alcohol 70%), 16 FL OZ (473.2 mL), Imported by: Dibar Labs, LLC,.Sugar Land, TX 77479, Distributed by: Lifetime Health Services, Pharr, TX 78577, Made in Mexico, NDC; 79284-005-00. UPC 8 60004 06470 1

Product Quantity:
Unknown quantity

Reason for Recall:
CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.

Recall Number:
D-0647-2021

Code Information:
All lots

Class II Drugs Event

Event ID:
88140

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
HOYU(US) LOGISTICS INC
2130 E Del Amo Blvd
Compton CA United States

Distribution Pattern:
Product was destroyed nationwide.

Associated Products

Product Description:
QiYu Hand Sanitizer (ethyl alcohol 75% (v/v)), 16.9 FL OZ (500 ML) bottles, Manufactured by: Guangzhou Minghui Cosmetics Co., Ltd, Baiyun District, Guanzhou, China Distributed by HoYu (US) Logistics Inc UPC 6 926645 716288

Product Quantity:
30,880 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0643-2021

Code Information:
Lot # Q20200320, exp. date 03/19/2022