

Enforcement Report - Week of February 8, 2023

Class I Drugs Event

Event ID:

91410

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

12/23/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

01/27/2023

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

GFA Production Xiamen Co. Ltd.

Huli Industrial Park No. 20 Meixi Road; Tong'An

Xiamen China

Distribution Pattern:

Nationwide and Canada.

Associated Products

Product Description:

Easy Care first aid Burn Cream (benzalkonium chloride 0.13% and lidocaine hydrochloride 0.5%), 0.9 g (0.03 oz) packets packaged in boxes of 10, Treatment for Burns, Made in China for Adventure Ready Brands, 944 Industrial Park Rd., Littleton, NH 03561, NDC 90107-0210, Product # 9999-1515

Product Quantity:

2880 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with *Bacillus lichenformis* and *Bacillus sonorensis*.

Recall Number:

D-0244-2023

Code Information:

Lot # W06I28, exp 09/28/2024

Product Description:

Adventure Marine 150, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 1015-0150

Product Quantity:

2016 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with *Bacillus lichenformis* and *Bacillus sonorensis*.

Recall Number:

D-0245-2023

Code Information:

Lot # W06I20, exp. date 09/20/2024

Product Description:

Adventure First Aid 1.0, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 0120-0213

Product Quantity:

60048 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with *Bacillus lichenformis* and *Bacillus*

sonorensis.

Recall Number:

D-0246-2023

Code Information:

Lot #: W06C05, exp 03/05/2024; W06F10, exp 06/10/2024; W06H15, exp 08/15/2024.

Product Description:

Adventure First Aid 1.5, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 0120-0212

Product Quantity:

75381 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0247-2023

Code Information:

Lot # W06H15, exp 08/15/2024

Product Description:

Easy Care First Aid 25 Person 2009 ANSI, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 9999-2129

Product Quantity:

37464 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0248-2023

Code Information:

Lot # W05L28, exp 12/28/2023

Product Description:

Easy Care First Aid 10 Person 2009 ANSI, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 9999-2128

Product Quantity:

194460 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0249-2023

Code Information:

Lot #: W05L28, exp 12/28/2023; W06F10, exp 06/10/2024; W06H15, exp 08/15/2024.

Product Description:

Easy Care First Aid Class A ANSI 25 Person, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 9999-2150

Product Quantity:

66400 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0250-2023

Code Information:

Lot #: W06C05, exp 03/05/2024; W06H15, exp 08/15/2024.

Product Description:

Easy Care First Aid 25 Person 2009 ANSI, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 9999-2132

Product Quantity:

8280 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0251-2023

Code Information:

Lot # W06H15, exp 08/15/2024

Product Description:

CVS First Aid Home, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 2980-0700

Product Quantity:

15000 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0252-2023

Code Information:

Lot # W06H15, exp 08/15/2024

Product Description:

Easy Care First Aid 10 Person 2009 ANSI, First Aid Kit, containing Easy Care first aid After Burn Cream 0.9 g packets, Product # 9999-2131

Product Quantity:

7200 packets

Reason for Recall:

Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.

Recall Number:

D-0253-2023

Code Information:

Lot # W06H15, exp 08/15/2024

Class II Drugs Event

Event ID:

91325

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Recall Initiation Date:

12/15/2022

Center Classification Date:

01/30/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Frenda Corporation
Calle A Lote 7 Parque Ind Las Cuevas
Trujillo Alto PR United States

Distribution Pattern:

Puerto Rico

Associated Products

Product Description:

Easy Clean Antiseptic Hand Sanitizer Solution 65% with Glycerine, 1 Gallon (128 Fl. oz.), Manufactured by: Frenda Corporation Trujillo Alto, PR 00976, UPC 8 91857 00050 9

Product Quantity:

144 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0254-2023

Code Information:

Lot: C013121

Product Description:

Easy Clean Alcohol Mult Surface Disinfecting Cleaner 75% Ethyl Alcohol, 32 FL. OZ. (946 mL.), Manufactured by: Frenda Corporation Trujillo Alto, PR 00976, UPC 8 91857 00052 3

Product Quantity:

8475 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0255-2023

Code Information:

Lots: C012821, C021421, C022121

Product Description:

Easy Clean Isopropyl Alcohol 99%, 1 Gallon (128 fl. oz.), Manufactured by: Frenda Corporation Trujillo Alto, PR 00976, UPC 8 91857 00054 7

Product Quantity:

164 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0256-2023

Code Information:

Lot: C030121

Product Description:

Easy Clean 70% Isopropyl Alcohol, packaged in a) 1 Gallon (128 fl. oz.) UPC 8 91857 00048 6; b) 16 fl. oz. (473 mL) UPC 8 91857 00047 9, Manufactured by: Frenda Corporation Trujillo Alto, PR 00976

Product Quantity:

65,376 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0257-2023

Code Information:

Lots: a)C011721, C011421, C021721, C021521, C021421, C060321, C060221, C042821, C042721, C022521, C011321; b) C011821, C011721, C052521, C051921, C052421, C030121, C022821

Product Description:

Easy Clean 75% Ethyl Alcohol, packaged in a) 1 Gallon (128 fl. oz.) UPC 8 91857 00045 5; b) 16 fl. oz. (473 mL) UPC 8 91857 00055 4; c) Rubbing Alcohol 10 fl. oz. (296 mL) UPC 8 91857 00044 8, Manufactured by Frenda Corporation Trujillo Alto, PR 00976

Product Quantity:

44,140 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0258-2023

Code Information:

Lots: a) C030121, C021121, C021021, C030121, C030221, C021721; b) C012721, C012621, C012521, C021721; c) C042721

Product Description:

Global Care Antibacterial Hand Sanitizer Alcohol Etilico 70% Original, 1 Gallon (128 FL OZ) 3785.41 mL, Dist. by Target Price, Inc. Catano, PR, UPC 8 70373 01326 2

Product Quantity:

124 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0259-2023

Code Information:

Lot: C013121

Product Description:

Global Care 70% Alcohol Ethyl Rubbing Alcohol, packaged in a) 32 FL OZ (946 mL) UPC 8 70373 01323 1; b) 16 FL OZ (473 mL) UPC 8 70373 01332 3; c) 1 Gallon (128 FL OZ) 3785.41 mL UPC 8 70373 01330 4, Dist. By Target Price, Inc. Catano, PR

Product Quantity:

12,130 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-0260-2023

Code Information:

Lots: a) C012821, C012721, C021821;b) C012521, C021721; c) C021121, C022121

Class II Drugs Event

Event ID:

91500

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/13/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/02/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States**Distribution Pattern:**

Nationwide in the U.S.

Associated Products

Product Description:

Diltiazem Hydrochloride Extended-Release Capsules, USP, 360 mg; Rx only; 90-count bottles, Manufactured by: Sun Pharmaceutical Industries Ltd.

Halol-Baroda Highway, Halol-389350, Gujarat, India; Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 47335-679-81

Product Quantity:

Lot # HAC3120A: 6912 Bottles; Lot # HAC3121A: 6792 Bottles; Lot # HAC4460A: 6816 Bottles; Lot # HAD0365A: 6744 Bottles; Lot # HAD1452A: 6840 Bottles

Reason for Recall:

Failed Impurity (Deacetyl Diltiazem Hydrochloride) specification during stability testing and failed dissolution testing at FDA laboratory.

Recall Number:

D-0262-2023

Code Information:

Lot #: HAC3120A, HAC3121A, Exp. 04/2023; HAC4460A, Exp. 10/2023; HAD0365A, Exp. 12/2023; HAD1452A, Exp. 02/2024.

Class II Drugs Event

Event ID:

91559

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/09/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/01/2023

Initial Firm Notification of Consignee or Public:

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:

DISCOVERY PHARMA LLC

815 Eyrie Dr Ste 3

Oviedo FL United States

Distribution Pattern:

CA, FL, WA

Associated Products

Product Description:

Conzerol zero molluscum contagiosum, Homeopathic treatment for Molluscum Contagiosum, Topical Cream, Net weight 0.78 oz (22g) tube, UPC 8 60322 00180 8, Manufactured by: Dr. Retter EC Warszawska 17, 05-075 Warszawa Poland

Product Quantity:

21,892 tubes

Reason for Recall:

CGMP deviations

Recall Number:

D-0261-2023

Code Information:

Lots: 22123 Exp. 01/2024; 21732 Exp. 07/2023