

Enforcement Report - Week of September 9, 2020

Class I Drugs Event

Event ID:
86037

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/11/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
AAA Cosmetica, SA de CV
Calle Recursos Hidraulicos 1 Pueblo La Loma, Tlalnepantla De Baz
Tlalnepantla Mexico

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

<p>Product Description: bio aaa Advance Hand Sanitizer Ethyl Alcohol 70%, Unscented, 16.23 Oz (480 mL), Distributed By: Payless Janitorial Corporation 1341 SW 21 Terrance, Fort Lauderdale, Florida Exported By: E. Audicode S.A. de C.V. Manufactured By: AAA Cosmetica S.A. de C.V. UPC 7 502272 12111 5</p> <p>Product Quantity: 204,768 bottles</p> <p>Reason for Recall: Chemical Contamination: Product contains methanol.</p> <p>Recall Number: D-1570-2020</p> <p>Code Information: Lots: 20DF9001, 20DF9002, 20DF9003, 20DF9004, 20DF9007, 20DF9008, 20DF9009, 20DF9010, 20DF9011, 20DF9012, 20DF9013, 20DF9014, 20DF9015, 20DF9016, 20DF9017, 20DF9018, 20DF9019, 20DF9020, 20DF9021, 20DF9022, EXP April 2022</p>
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Class I Drugs Event

Event ID:
86247

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/11/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional LLC
4901 Hiawatha Dr
Rockford IL United States

Distribution Pattern:
Nationwide

Associated Products

<p>Product Description: Amiodarone Hydrochloride Injection, USP, 450 mg/9 mL (50 mg/mL), 9 mL Single-Dose Vial (NDC 67457-153-99); 10 x 9 mL Single-Dose Vials</p>

per carton (NDC 67457-153-09), Rx only, Manufactured by: Mylan Institutional, Galway, Ireland; Manufactured for: Mylan Institutional LLC, Rockford, IL 61103.

Product Quantity:

13,682 cartons

Reason for Recall:

Labeling: Label Mix-Up; potential for cartons labeled as Tranexamic Acid Injection, USP to contain vials of Amiodarone HCl Injection, USP and cartons labeled as Amiodarone HCl Injection, USP to contain vials of Tranexamic Acid Injection, USP.

Recall Number:

D-1575-2020

Code Information:

Lot #: 191207, 191221, 191223 Exp. 11/2021; 200120 Exp. 12/2021

Product Description:

Tranexamic Acid Injection, USP, 1000 mg/10 mL (100 mg/mL), 10 mL Single-Dose Vial (NDC 67457-197-00); 10 x 10 mL Single-Dose Vials per carton (NDC 67457-197-10), Rx only, Manufactured by: Mylan Institutional, Galway, Ireland; Manufactured for: Mylan Institutional LLC, Rockford, IL 61103.

Product Quantity:

1407 cartons

Reason for Recall:

Labeling: Label Mix-Up; potential for cartons labeled as Tranexamic Acid Injection, USP to contain vials of Amiodarone HCl Injection, USP and cartons labeled as Amiodarone HCl Injection, USP to contain vials of Tranexamic Acid Injection, USP.

Recall Number:

D-1576-2020

Code Information:

Lot #: 191207, 191221, 191223, Exp. 11/2021; 200120 Exp. 12/2021

Class I Drugs Event

Event ID:

86270

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/14/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/11/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

SG24 LLC
8315 Rivoli Road Ste A
Bolingbroke GA United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

SkinGuard 24 All-Day Hand Sanitizer 2.67 oz. bottle with foam pump, Dist by: SG24 LLC, Bolingbroke, GA 31004 UPC 793573147103

Product Quantity:

9600 bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA; product labeled to contain 0.56% methanol making it an unapproved new drug

Recall Number:

D-1571-2020

Code Information:

SKU 051220024 All lots labeled to contain methanol

Product Description:

SkinGuard 24 All-Day Hand Sanitizer 8 oz. bottle with foam pump, Dist by: SG24 LLC, Bolingbroke, GA 31004 UPC 793573147125

Product Quantity:

9600 bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA; product labeled to contain 0.56% methanol making it an unapproved new drug

Recall Number:

D-1572-2020

Code Information:

SKU 051230024 All lots labeled to contain methanol

Product Description:

Skin Guard 24 All-Day Hand Sanitizer 10 mL Pocket Pen Dist by: SG24 LLC, Bolingbroke, GA 31004 UPC 793573147097

Product Quantity:

10,000 pens

Reason for Recall:

Marketed without an Approved NDA/ANDA; product labeled to contain 0.56% methanol making it an unapproved new drug

Recall Number:

D-1573-2020

Code Information:

SKU 051210048 All lots labeled to contain methanol

Product Description:

Skin Guard 24 All-Day Hand Sanitizer 1 4"x6" Hand Sanitizing Towelette packaged in 2.5 x 3.75 packets, Dist by: SG24 LLC, Bolingbroke, GA 31004

Product Quantity:

122,500 individual wipe packets

Reason for Recall:

Marketed without an Approved NDA/ANDA; product labeled to contain 0.56% methanol making it an unapproved new drug

Recall Number:

D-1574-2020

Code Information:

SKU 03150025 All lots labeled to contain methanol

Class II Drugs Event

Event ID:

86037

Status:

Ongoing

Recall Initiation Date:

07/02/2020

Center Classification Date:

09/11/2020

Recalling Firm:

AAA Cosmetica, SA de CV
 Calle Recursos Hidraulicos 1 Pueblo La Loma, Tlalnepantla De Baz
 Tlalnepantla Mexico

Distribution Pattern:

Distributed Nationwide in the USA

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

bio aaa Advance Hand Sanitizer Ethyl Alcohol 70%, Unscented, 16.23 Oz (480 mL), Distributed By: Payless Janitorial Corporation 1341 SW 21
 Terrance, Fort Lauderdale, Florida Exported By: E. Audicode S.A. de C.V. Manufactured By: AAA Cosmetica S.A. de C.V. UPC 7 502272 12111
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Product Quantity:

21,228 bottles

Reason for Recall:

CGMP Deviations

Recall Number:

D-1569-2020

Code Information:

Lots: All lots to include 20DF9005, 20DF9006, EXP April 2022

Class II Drugs Event

Event ID:

86042

Status:

Ongoing

Recall Initiation Date:

07/14/2020

Center Classification Date:

09/02/2020

Recalling Firm:

Soluciones Cosmeticas, SA de CV
Avenida Ano De Juarez 110 Otro Granjas San Antonio, Iztapalapa
Ciudad De Mexico Mexico

Distribution Pattern:

United States

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

Bersih Hand Sanitizer Gel, Net wt. 16.9 floz (500ml), Blue and Green cap) Distributed by RediBag USA 135 Fulton Ave New Hyde Park, NY 11040 UPC 8 16822 02666 7

Product Quantity:

2,486,400 bottles

Reason for Recall:

cGMP Deviations

Recall Number:

D-1560-2020

Code Information:

All lots remaining within expiry.

Class II Drugs Event

Event ID:

86167

Status:

Ongoing

Recall Initiation Date:

07/31/2020

Center Classification Date:

08/28/2020

Recalling Firm:

Laboratorios Jaloma S.A. de C.V.
Calle Aquiles Serdan No. 438 Col. Oblatos, Guadalajara
Guadalajara Mexico

Distribution Pattern:

Nationwide United States and Canada.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Press Release

Associated Products

Product Description:

Jaloma Antiseptic Hand Sanitizer, Ethyl Alcohol 62% with Vitamin E, packaged in a) 16.9 Fl. Oz. (1.06 pint, 500 mL), NDC# 65055-600-02, UPC# 759684515033, b) 4 Fl. Oz. (120 mL), NDC# 65055-600-01, UPC# 75968455026, Laboratorios Jaloma S.A. DE C.V., Aquiles Serdan 438, Z.P. 44380, Guadalajara, Jalisco, Mexico, Made in Mexico.

Product Quantity:

211,875 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-1555-2020

Code Information:

Lot # a) 0005295, Exp 4/2022, 0006373, Exp 5/2022; b) 0005412, Exp 4/2022, 0007134, Exp 5/2022, 0007834, Exp 5/2022, 0009239, Exp 6/2022

Class II Drugs Event

Event ID:

86172

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/04/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/31/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

ROQUE PLAST, S.A. DE C.V.
Cerrada Adolfo Manfredi 7 C
Atizapan De Zaragoza Mexico

Distribution Pattern:

Distributed Nationwide in the US

Associated Products

Product Description:

Command Brands GelAnti Bac Instant Hand Sanitizer, 70% Alcohol, , 8 FL OZ 250mL bottle, Roqueplast S.A. de C.V. Cda. Adolfo Manfredi #7 Altizapan de Zaragoza CP 52958 Edo de Mexico UPC 8 52239 00689 2

Product Quantity:

311,038 bottles

Reason for Recall:

CGMP Deviation: Potential contamination with undeclared methanol.

Recall Number:

D-1559-2020

Code Information:

Lots: 200371-12 Exp. 12/17/2023, 200371OH-05 Exp. 12/17/2023, 170420OH-06 Exp. 04/17/2023, 170420OH-8 Exp. 12/17/2023

Class II Drugs Event

Event ID:

86182

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/03/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/03/2020

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Leiper's Fork Distillery
3381 Southall Rd
Franklin TN United States

Distribution Pattern:

TN

Associated Products**Product Description:**

Leiper's Fork Distillery, Alcohol Antiseptic Topical Solution, Ethyl Alcohol 70%, packaged as a) 16 fluid oz./473.18 mL, bottle. b) 5 gallon vacuum sealed bucket. Leiper's Fork Distillery

Product Quantity:

1996 gallons

Reason for Recall:

Labeling Not Elsewhere Classified: Product labeled to contain methanol.

Recall Number:

D-1561-2020

Code Information:

All Lots

Class II Drugs Event**Event ID:**

86197

Status:

Ongoing

Recall Initiation Date:

08/07/2020

Center Classification Date:

08/28/2020

Recalling Firm:

Santa Cruz Biotechnology, Inc
10410 Finnell St
Dallas TX United States

Distribution Pattern:

U.S.A. Nationwide

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products**Product Description:**

UltraCruz Hand Sanitizing Gel Antimicrobial (70% Isopropyl Alcohol), packaged in 3 Fluid Oz./89 mL bottles, Manufactured By Santa Cruz Biotechnology, Inc. 10410 Finnell St. Dallas, TX 75220

Product Quantity:

14,238 bottles

Reason for Recall:

Subpotent drug

Recall Number:

D-1557-2020

Code Information:

Lot#: BF12530, Exp 05/11/2022

Class II Drugs Event**Event ID:**

86233

Status:

Ongoing

Product Type:

Drugs

Date Terminated:

Recall Initiation Date:

07/16/2020

Center Classification Date:

08/29/2020

Recalling Firm:

Grato Holdings, Inc.
201 Apple Blvd
Woodbine IA United States

Distribution Pattern:

One direct account in UT

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

E-Mail

Associated Products

Product Description:

HGH Vitality Homeopathic, 90 tablets, NDC 43742-1299-1, Dist. by Deseret Biologicals, Inc. 469 W. Parkland Drive, Sandy, UT 84070, NDC: 43742-1299-1

Product Quantity:

850 bottles

Reason for Recall:

Labeling: Error on Declared Strength

Recall Number:

D-1558-2020

Code Information:

Lot P2613