Enforcement Report - Week of September 8, 2021

Class I Drugs Event

Event ID:
87941

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/30/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Global Sanitizers LLC
5979 S Valley View Blvd
Las Vegas NV United States

Distribution Pattern:
Product Distributed Nationwide in the USA

Associated Products

Product Description:
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8 FL OZ (236 mL) bottle, Manufactured by Asiaticon, S.A. de C.V. Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC: 6 76753 00420 8,

Product Quantity:
50,000 bottles

Reason for Recall:
Chemical Contamination: FDA analysis found 1 lot of MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA (ethyl alcohol 70%) to be below the label claim for ethanol content and to contain methanol.

Recall Number:
D-0780-2021

Code Information:
Lot No: E082020, "Best Buy": 5/21/2022

Product Description:
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ / 250 mL bottle, Made in Mexico, Distributed by SBL Brands, LLC Las Vegas, NV 89119. UPC: 6 76753 00359 1

Product Quantity:

Reason for Recall:
Chemical Contamination: FDA analysis found 1 lot of MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA (ethyl alcohol 70%) to be below the label claim for ethanol content and to contain methanol.

Recall Number:
D-0781-2021

Code Information:
Lot No: E082020, "Best Buy": 5/21/2022

Class II Drugs Event

Event ID:
87496

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/02/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
China Gel Inc
501 W Golf Rd
Arlington Heights IL United States

Distribution Pattern:
Distributed Nationwide in the USA as well as Australia, Canada, France, Germany, Ireland, Norway, Turks & Caicos, Republic of Maldives, Russia, Singapore, Switzerland, United Kingdom

Associated Products

Product Description:
CHINA_GEL (Camphor 3.00%, Menthol 5.00%) A TOPICAL PAIN RELIEVER, packaged as a) 2 OZ (56.8g) tube, NDC 76305-300-13; b) 4 OZ (113.5g) jar, UPC 6 87806 10004 2, NDC 76305-300-02; c) 6 OZ (170 g) tube, UPC 6 87806 10006 2, NDC 76305-300-03; d) 8 OZ (226.8g) jar, UPC 6 87806 10008 2, NDC 76305-300-04; e) 16 OZ (453.6g), Bottle w/ Pump, UPC 6 87806 10016 7, NDC 76305-300-03; f) 128 OZ (3.78L) Gallon, UPC 6 87806 10128 7, NDC 76305-300-06; Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,

Product Quantity:
92,472 each

Reason for Recall:
CGMP deviations: Product being recalled as it was made in the same facility where contamination with B. cepacia was found in other products.

Recall Number:
D-0788-2021

Code Information:
Lot #: a)B122DY, exp 2021-05; B183GN, exp 2021-07; B262BF, exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04; C275CW, exp 2022-10; C338CH, exp 2022-12; b) B122DX, exp 2021-05; B183GP, exp 2021-07; B262BE, exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04; C275CW, exp 2022-10; C330BG, exp 2022-12 c) B122DY, exp 2021-05; B183GN, exp 2021-07; B262BF, exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04;C156FF, exp 2022-06; C247JB, exp 2022-09; C338CH, exp 2022-12. d)B122DX, Exp 05/2021; B122DY , EXP 05-2021; B183GP, EXP 07-2021; B262BE, EXP 09-2021; B262BF, EXP 09-2021; C002KF, EXP 01-2022; C030HT, EXP 02-2022; C094LT, EXP 04-2022; C156FF, EXP 06-2022; C247JB, EXP 09-2022; C275CW, EXP 10-2022; C330BG, EXP 12-2022; e) B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; f) B122DY , EXP 05-2021; B183GN, EXP 07-2021; B183GP, EXP 07-2021; B262BF, EXP 01-2022; C002KF, EXP 02-2022; C030HT, EXP 02-2022; C094LT, EXP 04-2022; C156FF, EXP 09-2022; C275CW, EXP 12-2022; C338CH, EXP 05-2022;

Product Description:
CHINA-GEL WHITE (Camphor 3.00%, Menthol 5.00%), A TOPICAL PAIN RELIEVER, packaged in a) 2 oz(56.8g) Tube, 76305-301-13 ; b) 4 oz (113.5 g) jar, UPC 6 87806 20004 1, NDC 76305-301-02 ; c) 6 OZ (170 g) tube, UPC 6 87806 20006 5, NDC 76305-301-03; d) 8 oz (226.8 g) Jar, UPC 6 87806 20008 9, NDC 76305-301-04; e) 16 oz (453.6 g) Bottle w/ Pump, UPC 6 87806 20016 4, NDC 76305-301-05; f) 120 oz (3.78L) gallon, UPC 6 87806 20128 4, NDC 76305-301-06: Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,

Product Quantity:
40,289 each

Reason for Recall:
CGMP deviations: Product being recalled as it was made in the same facility where contamination with B. cepacia was found in other products.

Recall Number:
D-0789-2021

Code Information:
Lot #: a)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; b)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; c)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; d)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; e)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; f)B100JS, Exp 04/2021; B183GQ, EXP 09-2021; B255KZ, EXP 09-2021; C030HS, EXP 04-2022; C100AH, EXP 06-2022; C247JF, EXP 10-2022;

Product Description:
aulief (Organic Camphor 3.00% Organic Menthol 5.00%), topical pain relief, packaged as a) 3.2 oz (90.7g) tube UPC 6 87806 30003 1 NDC 76305-302-01 ; b) 7.0 oz (198.5g) tube, UPC 6 87806 30007 9, NDC 76305-302-02; c) 16 oz (453.6g)Bottle w/ Pump, UPC 6 87806 30016 1, NDC 76305-302-03; Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,

Product Quantity:
3458 tubes

Reason for Recall:
CGMP deviations: Product being recalled as it was made in the same facility where contamination with B. cepacia was found in other products.

Recall Number:
D-0790-2021

Code Information:
Lot #: a) B136HN, Exp 05/2021; b) B136HN, Exp 05/2021; c) B136HN, Exp 05/2021

Class II Drugs Event

Event ID:
87941

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/30/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Global Sanitizers LLC
5979 S Valley View Blvd
Las Vegas NV United States

Distribution Pattern:
Product Distributed Nationwide in the USA

Associated Products

Product Description:
MEDICALLY MINDED ANTIMICROBIAL Hand Sanitizer Gel with Aloe Vera, (Ethyl Alcohol 70% v/v), 10 FL OZ / 300 mL, Manufactured by Grupo V-Klean S.A. de C.V, Calle Alborada 124, Parques del Pedregal, Tlalpan, 14250 Ciudad de Mexico, CDMX, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC: 6 76753 00417 8

Product Quantity:
50,000 bottles

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

Recall Number:
D-0778-2021

Code Information:
Lot No: GV4420205 Best By, 5/21/2022

Product Description:
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ (250 mL) bottle, Manufactured by Asiaticon, S.A. de C.V. Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC 6 76753 00414 7

Product Quantity:
50,000 bottles

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

Recall Number:
D-0779-2021

Code Information:
Lot No: E372020, "Best Buy": 5/21/2022;

Product Description:
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ / 250 mL bottle, Made in Mexico, Distributed by SBL Brands, LLC Las Vegas, NV 89119. UPC: 6 76753 00359 1 ,

Product Quantity:

Reason for Recall:
CGMP Deviations: lots and products of hand sanitizer are being recalled because they were manufactured under the same conditions as the

product lot found to contain methanol.

Recall Number:
D-0782-2021

Code Information:
Lot No: E212020, "Best Buy": 5/21/2022

Product Description:
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8 Fl OZ (236 mL) bottle, Manufactured by Asiaticon, S.A. de C.V. Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200. Distributed by SBL Brands, LLC Las Vegas, NV 89119 UPC: 6 76753 00420 8 ,

Product Quantity:

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

Recall Number:
D-0783-2021

Code Information:
Lot No: E332020, E212020 "Best Buy": 5/21/2022

Class II Drugs Event

Event ID:
88370

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/27/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, NDC 0591-3330-01

Product Quantity:
9,655 bottles

Reason for Recall:
CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for an excipient batch of Dibasic Calcium Phosphate.

Recall Number:
D-0774-2021

Code Information:
1408821A, exp. date 08/2023 (labeler - Teva)

Product Description:
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, NDC 70199-014-01

Product Quantity:
4,587 bottles

Reason for Recall:
CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for

an excipient batch of Dibasic Calcium Phosphate.

Recall Number:
D-0775-2021

Code Information:
1408822A, exp. date 08/2023 (labeler - Casper)

Product Description:
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, NDC 57237-266-01

Product Quantity:
4,992 bottles

Reason for Recall:
CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for an excipient batch of Dibasic Calcium Phosphate.

Recall Number:
D-0776-2021

Code Information:
1408824A, exp. date 08/2023 (labeler - Rising)

Class II Drugs Event

Event ID:
88391

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/31/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Clopidogrel Tablets, USP, 75 mg, 500-count bottle, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceutical Ltd., Baddi, Himachal, Pradesh, INDIA NDC 33342-060-15

Product Quantity:
444,000 tablets / 888 unit packs of 500 count

Reason for Recall:
Presence of foreign matter

Recall Number:
D-0787-2021

Code Information:
Lot # BCA82021A, Exp 06/2023

Class II Drugs Event

Event ID:
88475

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/27/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Granules USA, Inc.
35 Waterview Blvd Fl 3
Parsippany NJ United States

Distribution Pattern:
NY

Associated Products

Product Description:
Naproxen Sodum Tablets USP 220 mg, (Caplet), Manufactured by: Granules India Limited, Sy.No. 160/A, 161/E, 162, &174/A, Gagillapur Village, Dundigal-Gandimalsamma Monday, Medchai-Maikhajgir District - 500043, Telangana, INDIA. NDC 62207-762-36

Product Quantity:
11,450,000 tablets

Reason for Recall:
CGMP Deviations

Recall Number:
D-0777-2021

Code Information:
7620060a

Class II Drugs Event

Event ID:
88594

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/31/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Artificial Tears Ointment, Lubricant Eye Ointment, Net Wt. 3.5 g (1/8 oz.) per tube, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-062-35

Product Quantity:
142,188 tubes

Reason for Recall:
Non-Sterility - OOS sterility testing observed during 12-month controlled room temperature stability testing. The microbiological investigation identified the organism as a member of the Bacillus cereus group.

Recall Number:
D-0786-2021

Code Information:
Lot #: 9G01A, Exp 06/2022; 9H32A, Exp 07/2022; 9K82A, 9K82B, Exp 09/2022

Class III Drugs Event

Event ID:
88382

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/31/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Lidocaine Ointment USP, 5% Rx Only, Net Wt 35.44 g(1 1/4 oz)packaged in a laminat tube, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-008-14.

Product Quantity:
114,456 tubes

Reason for Recall:
Failed Viscosity Specifications: lot does not meet specification for Viscosity, which was determined through routine testing.

Recall Number:
D-0785-2021

Code Information:
Lot #: 15378, Exp 3/2023; 14418 EXP 10/2021

Class III Drugs Event

Event ID:
88523

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/20/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/31/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Donepezil HCL Tablets, USP, 5 mg, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd. India, Marketed by: Jubilant Cadista Pharmaceuticals Inc. Salisbury, MD 21801 NDC 59746-329-90

Product Quantity:
14,544 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0784-2021

Code Information:
Lot # DN120006A, exp. date 12/2021