Enforcement Report - Week of January 20, 2021

Class II Drugs Event

Event ID:
86898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/01/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
GAZA PROVEEDORA DE SERVICIOS DE HOSPEDAJE Y ALIMENTACION
Castilla 1473a Coloniajardines De Tonala
Tonala Mexico

Distribution Pattern:
TX

Associated Products

Product Description:
Pristine gel Hand Sanitizer Gel Antibacterial Gel Moisturizing, 8.45 Fl. Oz. (250 mL) Bottle, Distributed by: Universal Distributors LLC, 6197 S. Rural Rd.,Tempe AZ, 85283, Made in Mexico by: Gaza Proveedora De Servicios De Hospedaje y Alimentos S.A. de C.V., UPC 8 64972 00049 5, NDC 76540-100-02

Product Quantity:
26,000 liters

Reason for Recall:
cGMP deviations: Product made at the same facility where product tested was sub-potent.

Recall Number:
D-0229-2021

Code Information:
All Lots

Product Description:
Zapien Productos Hand Sanitizer Gel Antibacterial, 33.8 FL. OZ (1000 mL), Made by GAZA S.A. DE C.V. Castilla St. #1473-A ZIP 45410 Tonala, Jalisco, Mexico, UPC: 7 501700 623504, NDC numbers: 76938-001-01, 76938-001-02, 76938-001-03.

Product Quantity:
43875 liters

Reason for Recall:
cGMP deviations: Product made at the same facility where product tested was sub-potent.

Recall Number:
D-0230-2021

Code Information:
All Lots

Class II Drugs Event

Event ID:
87051

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2021

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 in the USA and Puerto Rico

Associated Products

Product Description:
Levetiracetam Oral Solution, 100 mg/mL, 16 fl oz (473 mL) bottle, Rx Only, HI-TECH PHARMACAL CO., INC., Amityville, NY 11701; NDC 50383-241-16

Product Quantity:
22,248 bottles

Reason for Recall:
Defective container: Customer complaints for oral solution leaking from bottles.

Recall Number:
D-0221-2021

Code Information:
Lot #: 373859, 373863, and 373865, Exp 05/2022; 374586, Exp 06/2022

Class II Drugs Event

Event ID:
87052

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2021

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

Recalling Firm:
Sunstar Americas, Inc.
301 E Central Rd
Schaumburg IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Paroex (Chlorhexidine Gluconate) Oral Rinse, USP 0.12%, Alcohol Free, Rx only, packaged in: a) 1 pint (473mL) NDC 52376-021-02; b) 4 fl oz (118 mL) NDC 052376-021-04, Sunstar Americas, Inc., Schaumburg, IL

Product Quantity:
a) 1,021,914 bottles; b) 255,552 bottles

Reason for Recall:
cGMP Deviations; FDA inspection of manufacturing facility observed potential Burkholderia cepacia complex (BCC) contamination, inadequate cleaning, inadequate microbiological testing, and insanitary conditions

Recall Number:
D-0222-2021

Code Information:
ALL LOTS with expiration date from Dec. 31, 2020 through Sep. 30, 2022

Class II Drugs Event

Event ID:
87080

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Nostrum Laboratories Inc
1800 N Topping Ave
Kansas City MO United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP, 750 mg, 100 tablets per bottle, Rx Only, Manufactured by: Nostrum Laboratories, Inc., Kansas City, MO 64120, NDC: 29033-056-01

Product Quantity:
6958 Bottles

Reason for Recall:
CGMP Deviations: detection of N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-0227-2021

Code Information:
MET200501 07/2022

Class II Drugs Event

Event ID:
87081

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/01/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/14/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Precision Dose Inc.
722 Progressive Ln
South Beloit IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Chlorhexidine Gluconate Oral Rinse USP 0.12%, packaged in a) 15 mL x 30 Unit Dose Cups (30-pack case) NDC 68094-028-61, b) 15 mL x 100 Unit Dose Cups (100-pack case) NDC 68094-028-62, Rx only, Precision Dose, Inc., South Beloit, IL 61080.

Product Quantity:
1,107,510 unit dose cups

Reason for Recall:
cGMP deviations: The firm was notified of the manufacturer's expanded recall.

Recall Number:
D-0228-2021

Code Information:
Lot #: a) 502037, 502040, 502043, Exp 1/31/2021; 502494, 502757, Exp 8/31/2021; 502677, Exp 9/30/2021; 502693, 502728, Exp 10/31/2021; 502771, 502784, Exp 11/30/2021; 502824, Exp 12/31/2021; 502925, Exp 2/28/2022; b) 502037, 502040, 502043, Exp 1/31/2021; 502494, Exp 8/31/2021; 502759, Exp 10/31/2021; 502771, Exp 11/30/2021

Class II Drugs Event

Event ID:
87115

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
03/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/12/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Edge Pharma, LLC
856 Hercules Dr
Colchester VT United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Methotrexate, USP Sterile Solution for Injection, Preservative Free 125mg/5ml (25mg/ml), 5 mL per syringe, Rx Only, SYRINGE FOR IM INJECTION, Edge Pharma, LLC 856 Hercules Dr. Colchester, VT 05446 Customer Service (USA) 1-802-992-1178, Barcode 0544650505

Product Quantity:
71 syringes

Reason for Recall:
Lack of Assurance of Sterility; the media used to conduct post-compounding sterility testing for the Methotrexate product was expired.

Recall Number:
D-0226-2021

Code Information:
Lot# 01-2020-28@10

Class III Drugs Event

Event ID:
86997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Compounding Inc
1270 Dons Ln
Conway AR United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Succinylcholine Chloride PF Inj. 200 mg/10 mL, 10 mL single use syringes, Rx only, US Compounding, 1270 Don's Lane, Conway, AR 72032

Product Quantity:
1534 syringes

Reason for Recall:
Labeling: Incorrect or Missing lot and/or expiration date: The lot number and BUD were printed in the incorrect position on the product label making it illegible.

Recall Number:
D-0223-2021

Code Information:
Lot #: 20202010@6 BUD: 02/17/2021

Class III Drugs Event

Event ID:
87020

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/18/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Benzhydrocodone and Acetaminophen Tablets, CII, 6.12mg/ 325mg, 100 Tablets, Rx Only, Manufactured for: KVK-Tech, Inc., Newtown, PA 18940 USA, NDC 10702-344-01

Product Quantity:
528 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification results obtained for N-Oxide impurity during the 12-month long term stability testing for Batch# 15892A

Recall Number:
D-0224-2021

Code Information:
Batch# 15892A, Exp, 2021-FEB

Class III Drugs Event

Event ID:
87044

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genus Lifesciences Inc.
514 N 12th St
Allentown PA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Oxycodone Hydrochloride Oral Solution, USP 5 mg/5mL unit dose cups, Rx Only, Genus Lifesciences Inc. NDC 64950-354-05 Case NDC: 64950-354-450(40 unit dose cups) Case NDC 64950-354-55 (50 unit dose cups)

Product Quantity:
1,171,550 cups

Reason for Recall:
Presence of Foreign Substance: Particulate matter was found in multiple lots of product.

Recall Number:
D-0231-2021

Code Information:
Lot # 35400119A, 35400219A, 35400319A, 35400419A , 35400519A , 35400619A, EXP 12/31/20; 35400719A, 35400819A, EXP 1/31/21; 35400919A, 35401019A, 35401119A, EXP 2/28/21; 35401219A, 35401319A, EXP 4/30/21; 35401419A, 35401519A, 35401619A, EXP 5/31/21; 35401719A, 35401819A, EXP 7/31/21; 35401919A, 35402019A, EXP 8/31/21; 35402119A, 35402219A, 35402319A, 35402419A, EXP 9/30/21; 35402519A, EXP 10/31/21; 35402619A, 35402719A, EXP 11/30/21; 35400120A, 35400220A, 35400320A, 35400420B, EXP 12/31/21; 35400520A, EXP 1/31/22, 35400620A, EXP 1/31/22.