Enforcement Report - Week of August 18, 2021

Class I Drugs Event

Event ID:
88291

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2021

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

Recalling Firm:
Med Shop Total Care Inc.
470 E Loop 281
Longview TX United States

Distribution Pattern:
Texas and Puerto Rico

Associated Products

Product Description:
BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 40MG-4000MCG/ML, 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0704-2021

Code Information:
Lot #: 09282020@94 BUD: 10/27/2020

Product Description:
BUPIVACAINE HCL-LIORESAL PF INJECTABLE 7.5MG-1625MCG/ML, 41 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
41 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0705-2021

Code Information:
Lot #: 09282020@38 BUD: 10/29/2020

Product Description:
FENTANYL-BUPIVACAINE HCL PF INJECTABLE 3000MCG-12MG/ML, 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0706-2021

Code Information:
Lot #: 09302020@67 BUD: 10/29/2020

Product Description:
FENTANYL-BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 575MCG-18MG-6000MCG/ML, 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0707-2021

Code Information:
Lot #: 09282020@75 BUD: 10/27/2020

Product Description:
HYDROMORPHONE HCL-BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 21 mL syringes in various strengths: a) 2.5MG-1.25MG-0.5MCG/ML, b) 10MG-5MG-10MCG/ML, c) 2MG-1MG-10MCG/ML, d) 10MG-5MG-10MCG/ML, e) 15MG-5MG-2000MCG/ML, f) 8MG-10MG-400MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
126 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0708-2021

Code Information:
Lot #: a)10012020@42, b) 10012020@43, c) 10012020@44, d) 10012020@46, e) 09302020@16, f) 09302020@44, BUD 10/29/2020

Product Description:
HYDROMORPHONE HCL-BUPIVACAINE HCL-CLONIDINE HCL PF INJECTABLE 21 mL syringes in two strengths: a) 20MG-20MG-60MCG/ML INJECTABLE, b) 5MG-5MG-100MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
42 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0709-2021

Code Information:
Lot #: a) 09302020@30, BUD 10/23/2020, b) 10022020@14, BUD 10/30/2020

Product Description:
MORPHINE-BUPIVACAINE PF INJECTABLE 21 mL, 22 mL, 23 mL, 41 mL and 43 mL syringes in various strengths: a) 20MG/ML-40MG/ML, b) 15MG-30MG/ML, c) 5MG/ML-20MG/ML, d) 2MG-30MG/ML, e) 20MG-5MG/ML, f) 15MG-5MG/ML, g) 5MG-2MG/ML, h) 5MG-11MG/ML, i) 20MG-6MG/ML, j) 10MG-10MG/ML, k) 6MG-4.8MG/ML, l) 30MG-10MG/ML, m) 5MG-4MG/ML, n) 10MG/ML-20MG/ML, o) 40MG-5MG/ML, p) 20MG-20MG/ML, q) 30MG-20MG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
466 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0710-2021

Code Information:
Lot #: a) 09282020@62, BUD 10/27/2020, 09302020@25, BUD 10/29/2020, b) 09292020@56, c) 09292020@58, d)09292020@60, e) 09292020@66, 09292020@73, f) 09292020@70, g) 09292020@71, h) 09292020@77, i) 09302020@20 j) 09302020@33, k) 09302020@48, l) 09302020@61, m) 09302020@66, n) 09302020@70, o) 09302020@26, BUD 10/29/2020, p) 10012020@8, q) 10022020@20, BUD 10/30/2020

Product Description:
HYDROMORPHONE HCL-BUPIVACAINE HCL-FENTANYL PF INJECTABLE 21 mL syringe in various strengths, a)10MG-20MG-100MCG/ML, b) 20MG-10MG-450MCG/ML, c) 13.3MG-3MG-3000MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
84 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0711-2021

Code Information:
Lot #: a) 09282020@66, BUD 10/27/2020, 09302020@42, BUD 10/29/2020, b) 09282020@79, c) 09292020@32, BUD 10/27/2020
09282020@66 09302020@42 09282020@79 09292020@32 10/27/2020 10/29/2020 10/27/2020 10/27/2020

Product Description:
MORPHINE-HYDROMORPHONE-BUPIVACAINE PF 13MG-19MG-2MG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop 470 E. Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0712-2021

Code Information:
Lot #: 09292020@64, BUD 10/28/2020

Product Description:
MORPHINE-BUPIVACAINE-KETAMINE PF INJECTABLE 21 mL syringe in two strengths: a) 5MG-25MG-5MG/ML, b) 1MG-2MG-100MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0713-2021

Code Information:
Lot #: 09302020@31, BUD 10/28/2020, b) 09302020@29, BUD 10/30/2020

Product Description:
SUFENTANIL-BUPIVACAINE-BACLOFEN PF 25MCG-12.5MG-750MCG/ML INJECTABLE 41 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
41 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0714-2021

Code Information:
Lot #: 09302020@47 BUD 10/28/2020

Product Description:
MORPHINE-BUPIVACAINE-FENTANYL PF 30MG-15MG-2000MCG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0715-2021

Code Information:
Lot #: 09302020@57 BUD 10/29/2020

Product Description:
HYDROMORPHONE HCL-BUPIVACAINE HCL-SUFENTANIL PF 25MG-9MG-110MCG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
21 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0716-2021

Code Information:
Lot #: 09292020@59 BUD 10/28/2020

Product Description:
HYDROMORPHONE HCL-BUPIVACAINE HCL PF INJECTABLE 21 and 22 mL syringes in various strengths: a) 0.5MG-5MG/ML, b) 2MG-35MG/ML, c) 25MG-15MG/ML, d) 6MG-1.5MG/ML, e) 3MG-3MG/ML, f) 5MG-15MG/ML, g)12MG-8MG/ML, h)2MG-2MG/ML, i) 30MG-30MG/ML, j) 8MG-20MG/ML, k) 20MG-10MG/ML, l)50MG-3.5MG/ML, m) 10MG-30MG/ML, n)15MG-1.6MG/ML, o) 20MG-30MG/ML, p)15MG-6MG/ML, q)15MG-27MG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605

Product Quantity:
360 mL

Reason for Recall:
Non-Sterility

Recall Number:
D-0717-2021

Code Information:
Lot #: a) 09302020@40, BUD 10/28/2020, b) 09292020@55, BUD 10/27/2020, c) 09302020@58, BUD 10/29/2020, d) 10012020@6, e) 09302020@23, f)10012020@4, g) 10012020@11 BUD 10/29/2020, h) 10012020@64, i)10022020@22, j) 10012020@15 BUD 10/30/2020, k) 10012020@41 BUD 10/29/2020, l) 09282020@92, BUD 10/27/2020, m)10012020@20 BUD 10/30/2020, n) 09302020@9, BUD 10/28/2020, o) 09292020@36, BUD 10/27/2020, p) 09302020@11, q) 09302020@18, BUD 10/28/2020

Class I Drugs Event

Event ID:
88340

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
People's Custom Rx and Clinical Care, LLC
785 E Brookhaven Cir
Memphis TN United States

Distribution Pattern:
MS, TN

Associated Products

Product Description:
C-PROGESTERONE OIL 100 MG/ML, 10 mL vials, Compound, People's Custom Rx, Compounded, Rx only, People's Custom Rx, 785 E Brookhaven Cir, Memphis, TN 38117

Product Quantity:
14 vials

Reason for Recall:
Non-Sterility

Recall Number:
D-0718-2021

Code Information:
Lot: 11649 BUD: 07/07/2021

Class II Drugs Event

Event ID:
88193

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/11/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eli Lilly & Company
839 S Delaware St
Indianapolis IN United States

Distribution Pattern:
OH, MS, IN

Associated Products

Product Description:
Zyprexa Intramuscular, Olanzapine for Injection, 10 MG per Single Use Vial, Rx only, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, NDC# 0002-7597-01

Product Quantity:
36,540 vials

Reason for Recall:
cGMP deviations: Atypical appearance, decrease in size and change in color of the lyophilized cake of drug product.

Recall Number:
D-0720-2021

Code Information:
Lot # 197

Class II Drugs Event

Event ID:
88227

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/07/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/10/2021

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Tablets, USP, 800mg/160mg Double Strength, 500 Tablets, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-HIghtstown Road, EAs Windsor, NJ 08520, Made in India, NDC 65862-420-05

Product Quantity:
3800 bottles

Reason for Recall:
Presence of Foreign Substance- Potential of metal contamination.

Recall Number:
D-0719-2021

Code Information:
Batch SP1D19082AA3 & Batch SP1D19085AA3; Exp 08/2022

Class II Drugs Event

Event ID:
88376

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/06/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Northstar Distribution Center 4853 Crumpler Rd. Memphis, TN 38141

Associated Products

Product Description:
Venlafaxine Tablets, USP 50 mg*, 100 Tablets Manufactured for Northstar Rx LLC Memphis, TN 38141 Manufactured by: ALKALOIDA Chemical Company Zrt. 4440 Tiszavasvari, Kabay Janos u.29.Hungary. Product of India NDC 16714-657-01

Product Quantity:
2856 bottles

Reason for Recall:
Presence of Forein Tablets/Capsules; Venlafaxine Tablets, USP 37.5 mg found in bottles labeled as Venlafaxine Tablets, USP, 50 mg

Recall Number:
D-0703-2021

Code Information:
AVK1175A, exp 9/2023

Class II Drugs Event

Event ID:
88392

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/12/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAI Holdings, LLC. dba Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville SC United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Nystatin Oral Suspension, USP 100,000 units per mL, Cherry/Peppermint Flavor, Rx ONLY, packaged in a) 16 fl oz (473 mL) NDC 0121-0868-16; b) 2 fl oz (60 mL) NDC 0121-0868-02; Manufactured by: Pharmaceutical Associates, Inc. Greenville, SC 29605

Product Quantity:
a) 1002 cases (12 bottles/case); b) 458 cases (24 bottles/case)

Reason for Recall:
Lack of CGMP: This recall is being carried out due to potential for carry over of Senna Syrup.

Recall Number:
D-0721-2021

Code Information:
Lots: a) C98F, C990 Exp. 30SEP2022, C9C2 Exp. 31OCT2022; b) C9E1 Exp. 31OCT2022

Product Description:
Cimetidine Hydrochloride Oral Solution 300 mg/5 mL, 8 fl oz (237 mL) Rx ONLY, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-0649-08

Product Quantity:
400 cases (12 bottles/case)

Reason for Recall:
Lack of CGMP: This recall is being carried out due to potential for carry over of Senna Syrup.

Recall Number:
D-0722-2021

Code Information:
Lot: C62F Exp. 31OCT2022

Product Description:
Ethosuximide Oral Solution USP 250 mg/5 mL, 16 fl oz (473 mL), Rx ONLY, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-0670-16

Product Quantity:
75 cases (6 bottles/case)

Reason for Recall:
Lack of CGMP: This recall is being carried out due to potential for carry over of Senna Syrup.

Recall Number:
D-0723-2021

Code Information:
Lot: C9BC Exp. 31OCT2022