Enforcement Report - Week of March 23, 2022

Class II Drugs Event

Event ID:
89663

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/14/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17187 N Laurel Park Dr Ste 300
Livonia MI United States

Distribution Pattern:
Nationwide within USA

Associated Products

Product Description:
hydrALAZINE HCl Tablets, USP, 10 mg, 100 Tablets per carton (10x10 blister packs), Rx only, Distributed by: MAJOR PHARMACEUTICALS, Livonia, MI 48152 USA. NDC # 0904-6440-61

Product Quantity:
5,953 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification result obtained during routine stability testing for Impurities.

Recall Number:
D-0653-2022

Code Information:
Lot #: T03755, T03756, Exp. Date 03/2023

Class II Drugs Event

Event ID:
89665

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2022

Initial Firm Notification of Consignee or Public:
Other

Recalling Firm:
B. Braun Medical, Inc.
901 Marcon Blvd
Allentown PA United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP, 250 mL Excel Container, Rx only, B. Braun Medical Inc., Bethlehem, PA, NDC 0264-7800-20

Product Quantity:
33,742 bags

Reason for Recall:
Lack of sterility assurance: leaking bags

Recall Number:
D-0655-2022

Code Information:
Lot #: J1E086, J1E204, J1E213, Exp 5/31/2023; J1H137, J1H138, Exp 6/30/2023

Class II Drugs Event

Event ID:
89712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/15/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Distributed to 1 wholesaler/distributor

Associated Products

Product Description:
Alprazolam Tablets, USP 1mg, 180-count bottles, Rx only, Manufactured by ULTRAlab Laboratories, Inc., NY; Packaged by GSMS, Inc., CA NDC 60429-504-18.

Product Quantity:
401 bottles

Reason for Recall:
CGMP Deviation: Potential cross-contamination with other drug substance during the manufacturing process.

Recall Number:
D-0654-2022

Code Information:
Lot #: GS027852, Expiry: 06/2022.

Class II Drugs Event

Event ID:
89773

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/06/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/17/2022

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Family Pharmacy of Statesville
3478 E Broad St
Statesville NC United States

Distribution Pattern:
NC only

Associated Products

Product Description:
Hydromorphone HCl 2 mg/mL Infusion 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
2 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0656-2022

Code Information:
Lot #: 07212020@4 BUD: 10/19/2020; 07212020@4 BUD: 10/30/2020

Product Description:
Hydromorphone HCl 1 mg/mL 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
4 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0657-2022

Code Information:
Lot #: 07272020@2 BUD: 10/25/2020; 07302020@1 BUD: 10/28/2020; 08012020@1 BUD: 10/30/2020

Product Description:
Hydromorphone HCl 5 mg/mL Infusion in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
1 bag

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0658-2022

Code Information:
Lot #: 07292020@7 BUD: 8/12/2020

Product Description:
Hydromorphone HCl 0.1 mg/mL Infusion in 1000 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
1 bag

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0659-2022

Code Information:
Lot #: 08022020@1 BUD: 8/17/2020

Product Description:
Trimix (Alprostadil/Papaverine/Phentolamine) 20 mcg/30 mg/0.5 mg Injectable 5 mL vials, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0660-2022

Code Information:
Lot #: 07212020@ BUD: 9/4/2020

Product Description:
Trimix (Alprostadil/Papaverine/Phentolamine) 10 mcg/20 mg/1 mg Injectable 5 mL vials, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0661-2022

Code Information:
Lot #:07232020@1 BUD: 9/6/2020; 07282020@1 BUD: 9/11/2020; 07282020@2 BUD: 9/11/2020

Product Description:
Vancomycin14 mg/mL Fortified Ophthalmic Solution in 5 mL bottles, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
3 bottles

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0662-2022

Code Information:
Lot: 07312020@2 BUD: 9/14/2020

Product Description:
Morphine Sulfate 6 mg/mL Infusion in 250 mL bag, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
8 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0663-2022

Code Information:
Lot #: 07212020@3 BUD: 10/19/2020; 07292020@2 BUD: 10/27/2020

Product Description:
Ketamine 50 mg Infusion (LV 1) Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
3 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0664-2022

Code Information:
Lot #: 07212020@1 BUD: 8/4/2020; 07232020@2 BUD: 8/6/2020; 07302020@2 BUD: 8/13/2020

Product Description:
Lorazepam 1 mg/mL Infusion Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
1 bag

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0665-2022

Code Information:
Lot #: 07312020@6 BUD: 8/7/2020

Product Description:
Methylcobalamin 1 mg/mL Injectable in 1 mL syringes, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
5 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0666-2022

Code Information:
Lot #: 07282020@3 BUD: 8/11/2020

Product Description:
Fentanyl 150 mcg/mL Infusion Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.

Product Quantity:
1 bag

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0667-2022

Code Information:
Lot #: 07312020@5 BUD: 8/14/2020

Not Yet Classified Drugs Event

Event ID:
89686

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Walmart Stores
805 Moberly Ln
Bentonville AR United States

Distribution Pattern:
Nationwide in the USA via www.walmart.com

Associated Products

Product Description:
Avaphinal Maximum Male Enhancement Sexual Pills, 2000 MG*, packaged in 10 Capsules per carton.

Product Quantity:
unknown

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared sildenafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
Lot: DK1027, Exp 08/01/2023