Enforcement Report - Week of February 23, 2022

Class I Drugs Event

Event ID:
89550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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

Recalling Firm:
STAQ Pharma, Inc.
14135 E 42nd Ave Ste 50
Denver CO United States

Distribution Pattern:
CO, OH, and TX.

Associated Products

Product Description:
Hydromorphone HCL PF 10 mg/50 mL (0.2 mg/mL) in NaCL, 50 mL in 50 mL Syringe, Injection for IV Use Only, This is a compounded drug, Not for Resale, Office Use Only, Single Dose, Sterile Product, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0104-05.

Product Quantity:
905 Syringes

Reason for Recall:
Labeling; label mix-up; A limited number of syringes containing Hydromorphone 0.2 mg/mL 50 mL, were mislabeled with Morphine 1 mg/mL 25 mL syringe labels, lot number: 21104221A.

Recall Number:

Code Information:
Lot Number: 21104221A, Expiration date: 05-22-2022

Product Description:
Morphine Sulfate 25 mg/25 mL (1 mg/mL) in NaCl, 25 mL in 30 mL Syringe, For IV Use Only. This is a compounded drug, Not for Resale, Office Use Only, Single Dose, Sterile Product, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0105-04.

Product Quantity:
n/a

Reason for Recall:
Labeling; label mix-up; A limited number of syringes containing Hydromorphone 0.2 mg/mL 50 mL, were mislabeled with Morphine 1 mg/mL 25 mL syringe labels, lot number: 21104221A.

Recall Number:

Code Information:
Lot Number: 21104221A, Expiration date: 05-22-2022

Class I Drugs Event

Event ID:
89558

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/17/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
ABC Sales 1 Inc
116 Adar Ct
Monsey NY United States

Distribution Pattern:
Product was distributed nationwide in the USA via Amazon Marketplace.

Associated Products

Product Description:
MAC DADDY RED Capsules, packaged in 10-count blisters per carton, ASIN B07TLDZLY2, UPC 742137 605191.

Product Quantity:
565 cartons

Reason for Recall:
Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.

Recall Number:
D-0562-2022

Code Information:
Lot # 1230004, Exp. date 03/30/2024

Product Description:
MAC DADDY PURPLE Capsules, packaged in 10-count blisters per carton, ASIN B08Z63Z4QK, UPC 742137 605764.

Product Quantity:
336 cartons

Reason for Recall:
Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.

Recall Number:
D-0563-2022

Code Information:
Lot # 1230005, Exp. date 03/30/2024

Class II Drugs Event

Event ID:
89231

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/14/2022

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Organics Corporation of America DBA Ambix Laboratories
55 W End Rd
Totowa NJ United States

Distribution Pattern:
The product went to one consignee. Natural Organics, Inc., 548 Broadhollow Rd., Melville, NY 11747.

Associated Products

Product Description:
NaturesPlus Advanced Therapeutics Glucosamine Chondroitin MSM Ultra Rx- Joint Cream, 4 oz tubes, Manufactured for NaturesPlus 548 Broadhollow Road, Melville, NY 11747, USA

Product Quantity:
4,214 tubes

Reason for Recall:
MICROBIAL CONTAMINATION OF NON-STERILE PRODUCT: microbial contaminant identified as Pluralibacter gergoviae.

Recall Number:
D-0559-2022

Code Information:
Product code 4929, Lot # 23622

Class II Drugs Event

Event ID:
89423

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/14/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Moxifloxacin Ophthalmic Solution, USP 0.5% w/v, 3 mL bottle, Sterile, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ 08520, Made in India, NDC 65862-840-03

Product Quantity:
115776 bottles

Reason for Recall:
Failed impurities/degradation specifications -Out of Specification (OOS) results of 0.78% to 1.02%; Spec NMT 0.1% for Other Single impurities

Recall Number:
D-0560-2022

Code Information:
Lot#: CMF210001, CMF210003, CMF210004, Exp 6/2023

Class II Drugs Event

Event ID:
89551

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/09/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/14/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company, Inc.
9000 State Rd
Philadelphia PA United States

Distribution Pattern:
Product was distributed nationwide in the USA.

Associated Products

Product Description:
Diazepam Oral Solution (Concentrate), 25 mg per 5 mL (5 mg/mL), 30 mL BOTTLE and DROPPER, Rx Only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136, NDC 0527-1768-36.

Product Quantity:
23,598 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification results for related substances.

Recall Number:
D-0558-2022

Code Information:
Lot #: 2664A, 2664B, Exp. date 07/2022; 2874A, 2874B, Exp. date 01/2023

Class II Drugs Event

Event ID:
89556

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ANI Pharmaceuticals, Inc.
210 W Main St
Baudette MN United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Alprazolam Tablets, USP 0.25 mg, packaged in a) 100-count bottles (NDC 67253-900-10), b) 500-count bottles (NDC 67253-900-50), and c) 1000-count bottles (NDC 67253-900-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977

Product Quantity:
73,920 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0564-2022

Code Information:
Lot #: a) 19C003A, Exp. Date 03/2022; 19G002A, exp. date 07/2022; b) 19C004B, Exp. Date 03/2022; c) 19C048C, Exp. Date 03/2022

Product Description:
Alprazolam Tablets, USP 0.5 mg, packaged in a) 100-count bottles (NDC 67253-901-10), b) 500-count bottles (NDC 67253-901-50), and c) 1000-count bottles (NDC 67253-901-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977

Product Quantity:
205,662 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0565-2022

Code Information:
Lot #: a) 19B029A, Exp. Date 02/2022; 19D021A, Exp. Date 04/2022. b) 19A087B, 19A088B, 19A089B, 19A090B, Exp. Date 02/2022; 19A086B, 19A091B, 19B019B, Exp. Date 02/2022. c) 19B020C, 19B021C, 19B027C, 19B028C, Exp. Date 02/2022, 19E056C, 19E057C, Exp. Date 05/2022; 19E059C, Exp. Date 06/2022 19G072C, Exp. Date 07/2022

Product Description:
Alprazolam Tablets, USP 1.0 mg, packaged in a) 100-count bottles (NDC 67253-902-10), b) 500-count bottles (NDC 67253-902-50), and c) 1000-count bottles (NDC 67253-902-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977

Product Quantity:
173,499 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0566-2022

Code Information:
Lot #: a) 19B081A, Exp. Date 02/2022; 19E088A, 19E089A, Exp. Date 05/2022 b) 19A102B, Exp. Date 02/2022; 19D067B, 19D068B, Exp. Date 04/2022; 19D070C, Exp. Date 05/2022. c) 19F045C, 19F046C, Exp. Date 06/2022; 19B082C, 19B083C, Exp. Date 03/2022; 19D069C, Exp. Date 05/2022.

Product Description:
Alprazolam Tablets, USP 2.0 mg, packaged in a) 100-count bottles (NDC 67253-903-10), b) 500-count bottles (NDC 67253-903-50), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977

Product Quantity:
70,788 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0567-2022

Code Information:
Lot #: a) 19C002A, Exp. Date 03/2022; 19E012A, 19E013A, Exp. Date 05/2022. b) 19C100B, Exp. Date 04/2022; 19E001B, 19E002B, Exp. Date 05/2022.

Product Description:
Pyrazinamide Tablets, USP 500 mg, 100-count bottles, Rx only, Manufactured by: ULTRAtab Laboratories, Inc. Highland, NY 12528, Distributed by Par Pharmaceuticals, Chestnut Ridge, NY 10977, NDC 67253-660-10.

Product Quantity:
5,477 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0568-2022

Code Information:
Lot #: 19B064A, Exp. Date 03/2022

Not Yet Classified Drugs Event

Event ID: **Product Type:**

88409

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Je Dois Lavoir LLC
3936 E Evergreen Ave
Visalia CA United States

Distribution Pattern:
Sold online via website nationwide in the USA and Canada.

Associated Products

Product Description:
365 SKINNY High Intensity Capsules, 600 mg, 30-count bottle, BODY BALANCE INTERNACIONAL

Product Quantity:
783 bottles

Reason for Recall:
Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared sibutramine, a previously approved drug that was withdrawn from the US market due to safety concerns.

Recall Number:

Code Information:
Lot 102-26, Exp Dec 2022

Not Yet Classified Drugs Event

Event ID:
89462

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CooperSurgical, Inc
825 Wurlitzer Dr
North Tonawanda NY United States

Distribution Pattern:
Product was distributed to one distribution center that may have further distributed the product nationwide.

Associated Products

Product Description:
Paragard T 380A (Intrauterine Copper Contraceptive), package in cartons containing one sterile unit together with an insertion tube and solid white rod in a Tyvek polyethylene pouch, Rx only, Manufactured by Teva Women's Health Inc. a subsidiary of Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 51285-204-01

Product Quantity:
48,645 cartons

Reason for Recall:
Non-sterility

Recall Number:

Code Information:
Lot # 517001,Exp 1/2024

Not Yet Classified Drugs Event

Event ID:
89529

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide with the United States

Associated Products

Product Description:
Chlorthalidone Tablets USP 25 mg, Rx Only, 100 Tablets, Sun Pharma, Mfg. by: Fontida Bio Pharm Inc., 1100 Orthodox St. Philadephia, PA 19124, Dist. by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 57664-648-88.

Product Quantity:
59,232 bottles

Reason for Recall:
Foreign Matter

Recall Number:

Code Information:
Lot #: P0602, Exp. Date 03/2023

Not Yet Classified Drugs Event

Event ID:
89560

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Erythromycin Topical Gel USP, 2%, Net Wt 30 g tube, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, Distributed by:

McKesson Corporation, dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-053-66.

Product Quantity:
11040 tubes

Reason for Recall:
Failed Impurities/Degradation Specifications: Lot not meeting specification for Unknown Max Related Compounds.

Recall Number:

Code Information:
Lot: 15724, Exp. 06/2022

Not Yet Classified Drugs Event

Event ID:
89563

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Celebrate Today
143 Front Ave
Brentwood NY United States

Distribution Pattern:
Product was distributed nationwide in the USA via Amazon Marketplace

Associated Products

Product Description:
RED MAMMOTH capsules, 400 mg, packaged in 10-count blisters per carton, ASIN B00KA8FBNI, barcode X001ANE0I5.

Product Quantity:
500 cartons

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared sildenafil and tadalafil, ingredients 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

Not Yet Classified Drugs Event

Event ID:
89579

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Your Favorite Shop
14 Imperial Pl
Jackson NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA via the internet through Amazon Marketplace.

Associated Products

Product Description:
THE RED PILL, EXTRA STRENGTH capsules, 800 mg, packaged in 10-count blisters packaged in a carton, ASIN B0847BSQQ5, Barcode X002G5GMJ1.

Product Quantity:
12,500 cartons

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

Recall Number:

Code Information:
Lot # 26436989, Exp. date 10/30/2023

Not Yet Classified Drugs Event

Event ID:
89591

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Revive Rx LLC dba Revive Rx Pharmacy
3831 Golf Dr Ste A
Houston TX United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
HCG 6,000iu (lyo) Human Chorionic Gonadotropin Inj., For Sub-Q or IM Use Only, Not For IV Use, Rx Only, 88888-1739-01, Compounded by: Compounded By: Revive Rx 3831 Golf Dr., Houston, TX 77018.

Product Quantity:
115 vials

Reason for Recall:
Non-sterility.

Recall Number:

Code Information:
Lot: 631359 BUD: 05/01/2022