Enforcement Report - Week of May 18, 2022

Class I Drugs Event

Event ID:
89805

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/09/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Nationwide USA and Puerto Rico, Canada, Columbia, France

Associated Products

Product Description:
SyrSpend SF Suspending Base, Cherry Flavored, packaged in a) 500mL bottles (NDC 51552-1123-5) and b) 4L bottles (NDC 51552-1123-9), Rx Only, Manufactured for Fagron, Inc., St. Paul, MN 55120.

Product Quantity:
a) 559 bottles and b) 243 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Product: Product is contaminated with Burkholderia gladioli.

Recall Number:
D-0856-2022

Code Information:
Lot #: a) A67185, Exp. Date 08/31/2024; b) Lot #: A67186, Exp. Date 08/31/2024

Class II Drugs Event

Event ID:
89930

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/11/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
1718 Northrock Ct
Rockford IL United States

Distribution Pattern:
Nationwide within USA

Associated Products

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules, USP 20 mg, packaged in Unit Dose Blister Cards of 6 (10 cards of 6 Capsules each per carton), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC 42292-009-16

Product Quantity:
555 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: OOS result was obtained for Any Other Individual Impurity at the 12M room temperature time point.

Recall Number:
D-0860-2022

Code Information:
Lot #: 3112743, Exp. Date 4/30/2023; 3112582, Exp. Date 3/31/2023; 3110438, 3111708, 3111120, Exp. Date 7/31/2022

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules, USP 40 mg, packaged in Unit Dose Blister Cards of 6 (10 cards of 6 Capsules each per carton), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC 42292-010-16

Product Quantity:
885 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: OOS result was obtained for Any Other Individual Impurity at the 12M room temperature time point.

Recall Number:
D-0861-2022

Code Information:
Lot #: 3110437, 3111409, 3110785, Exp. Date 7/31/2022; 3112173, Exp. Date 11/30/2022

Class II Drugs Event

Event ID:
90091

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg PA United States

Distribution Pattern:
Product was distributed nationwide in the USA

Associated Products

Product Description:
Xanax XR (alprazolam) extended-release tablets, 3 mg, 60-count bottle, Rx only, Distributed by Pharmacia & Upjohn Co, Division of Fizer Inc, NY, NY 10017, NDC 0009-0068-07.

Product Quantity:
110 bottles

Reason for Recall:
Failed Dissolution Specifications: low out of specification results for dissolution.

Recall Number:
D-0854-2022

Code Information:
Lot #: DX7983, exp. date 02/28/2023

Class II Drugs Event

Event ID:
90112

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/02/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/09/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amgen, Inc.
1 Amgen Center Dr
Thousand Oaks CA United States

Distribution Pattern:
Nationwide in the USA, Egypt and Lithuania.

Associated Products

Product Description:
MVASI (bevacizumab-awwb), Injection, For Intravenous Infusion After Dilution, 100 mg/4 ml, Single dose vial, Rx only, Manufactured by Amgen Inc. Thousand Oaks, CA 91320-1799, NDC 55513-0206-01

Product Quantity:
15,823

Reason for Recall:
Defective container: loose crimp defect, potential loss of container integrity.

Recall Number:
D-0855-2022

Code Information:
Lots: 1142258, 1143196, Exp. 09/24

Class II Drugs Event

Event ID:
90167

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/11/2022

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

Recalling Firm:
Lula Holdings L.L.C.
1532 Saint Charles Ave
New Orleans LA United States

Distribution Pattern:
LA

Associated Products

Product Description:
Kill 'Dat Sanitizing Products Hand Sanitizer, 1 gallon (128 fl. oz.) 80% Alcohol, OTC, Manufactured by: Lula Holdings LLC, 15532 St. Charles Avenue, New Orleans, LA, NDC 77348-001-02.

Product Quantity:
192.78 pounds

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetaldehyde above specification limits.

Recall Number:
D-0859-2022

Code Information:
Batch 39

Class III Drugs Event

Event ID:
89797

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/11/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Nandrolone Decanoate, USP, 100 g per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-04

Product Quantity:
58 containers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0862-2022

Code Information:
Lot #: 18H02-U02-044979, 18H02-U02-046141, Exp. Date 10/31/2022; 18L12-U02-050309,18L12-U02-000953, 18L12-U02-A009829, Exp. Date Sep 2023.

Product Description:
Nandrolone Decanoate, USP, 500 g per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-05

Product Quantity:
53 containers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0863-2022

Code Information:
Lot #: 18H02-U02-044978, 18L12-U02-050018, Exp. Date 10/31/2022 18L12-U02-000952, Exp. Date Sep 2023

Product Description:
Nandrolone Decanoate, USP, 1 kg per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-07

Product Quantity:
68 containers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0864-2022

Code Information:
Lot #: 18H02-U02-044977, 18H02-U02-046140, 18L12-U02-050572, Exp. Date 10/31/2022; 18L12-U02-050308, 18L12-U02-000951, Exp. Date Sep 2023

Product Description:
Nandrolone Decanoate, USP, 500 g per plastic container, Rx Only, For Prescription Compounding, Distributed by: Humco, 7400 Alumax Road, Texarkana, TX 75501. NDC 0395-8212-56

Product Quantity:
2 containers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0865-2022

Code Information:
Lot #: 18L12-U02-050018, Exp. Date 10/31/2022

Product Description:
Nandrolone Decanoate, USP, 1 kg per plastic container, Rx Only, For Prescription Compounding, Distributed by: Humco, 7400 Alumax Road, Texarkana, TX 75501. NDC 0395-8212-43

Product Quantity:
1 containers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0866-2022

Code Information:
Lot #: 18L12-U02-050019, Exp. Date 10/31/2022

Class III Drugs Event

Event ID:
90088

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/10/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
buPROPion Hydrochloride Extended-Release Tablet, USP (SR), 150 mg packaged in a) 60-count bottle (47335-737-86), b)100-count bottle (47335-737-88), c)500-count bottle (47335-737-13), Rx only Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India

Product Quantity:
9804 bottles

Reason for Recall:
Presence Of Foreign Substance: Customer complaint for the presence of dark, gritty substance found within the bottle which was determined to be activated carbon from the desiccant canister inside the bottle.

Recall Number:
D-0857-2022

Code Information:
Lot #: a) JKX5126A, JKX5127A, JKX5128A, Exp 10/2022; b) JKX5126B , JKX5128B, Exp 10/2022; c)JKX5126C, JKX5127C, JKX5128C, Exp 10/2022;

Product Description:
buPROPion Hydrochloride Extended-Release Tablet, USP (SR), 200 mg, 60-count bottle, Rx only Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 47335-738-86

Product Quantity:
744 bottles

Reason for Recall:
Presence Of Foreign Substance: Customer complaint for the presence of dark, gritty substance found within the bottle which was determined to be activated carbon from the desiccant canister inside the bottle.

Recall Number:
D-0858-2022

Code Information:
Lot #: HAC2237A, exp. date 05/2023