Enforcement Report - Week of April 6, 2022

Class II Drugs Event

Event ID:
89808

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/23/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Drug Depot, Inc., dba APS Pharmacy
34911 Us Highway 19 N Ste 600
Palm Harbor FL United States

Distribution Pattern:
Nationwide in the USA including Puerto Rico.

Associated Products

Product Description:
GONADORELIN (5ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID132227, APS Pharmacy

Product Quantity:
6017 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0728-2022

Code Information:
Lots: 745708 BUD: 6/21/2022; 753364 BUD: 7/27/2022; 752508 BUD: 7/24/2022; 750313 BUD: 7/16/2022; 753020 BUD: 7/26/2022; 747712 BUD: 7/4/2022; 747974 BUD: 7/5/2022; 754802 BUD: 8/3/2022; 751158 BUD: 7/19/2022; 756837 BUD: 8/16/2022; 748939 BUD: 7/10/2022; 750842 BUD: 7/18/2022; 755742 BUD: 8/8/2022; 758691 BUD: 8/28/2022; 758432 BUD: 8/27/2022; 758975 BUD: 8/29/2022; 756643 BUD: 8/15/2022

Product Description:
(CA) GONADORELIN (4ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID136345, APS Pharmacy

Product Quantity:
1843 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0729-2022

Code Information:
Lots: 749842 BUD: 7/13/2022; 749568 BUD: 7/12/2022; 752053 BUD: 7/23/2022; 752817 BUD: 7/25/2022; 757404 BUD: 8/21/2022; 757915 BUD: 8/23/2022; 757321 BUD: 8/20/2022; 753718 BUD: 7/30/2022

Product Description:
TESTOSTERONE CYPIONATE/ANASTROZOLE *GS* OIL 200MG/1MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 4 ML Formula ID 115387; b) (RM) 10 ML Formula ID 115125; APS Pharmacy

Product Quantity:
846 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0730-2022

Code Information:
Lots: a) 745383 BUD: 6/20/2022; 759295 BUD: 8/30/2022; b) 745749 BUD: 6/21/2022; 746272 BUD: 6/27/2022

Product Description:
TESTOSTERONE CYPIONATE/ ANASTROZOLE *GS* OIL (10ML) 200MG/0.5MG/ML; Packaged in a multi dose 10ML vial, as a) (CA) 4 ML Formula ID 136164; b) (RM) 10 ML Formula ID 115962; APS Phar

Product Quantity:
73 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0731-2022

Code Information:
Lots: a)750851 BUD: 7/18/2022; b) 754549 BUD: 8/2/2022

Product Description:
TESTOSTERONE CYPIONATE/ DHEA *GS* 200/10MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 5 ML Formula ID 115678; b) 10 ML Formula ID 115498, APS Pharmacy

Product Quantity:
620 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0732-2022

Code Information:
Lots: a)746000 BUD: 6/26/2022; b) 751472 BUD: 7/20/2022

Product Description:
TESTOSTERONE CYPIONATE/PROPIONATE *SES* Oil (10 ML) 160MG/20MG/ML Injectable, Packaged in a multi dose 10ml vial, Formula ID 115498, APS Pharmacy

Product Quantity:
0

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0733-2022

Code Information:
Lot:759312 BUD: 8/30/2022

Product Description:
TESTOSTERONE CYPIONATE *GS* Oil 200 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 76681, APS Pharmacy

Product Quantity:
24 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0734-2022

Code Information:
Lot: 754381 BUD: 8/1/2022

Product Description:
TESTOSTERONE CYPIONATE *GS* (2 mL) 80 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 127492, APS Pharmacy

Product Quantity:
17 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0735-2022

Code Information:
Lot: 746269 BUD: 6/27/2022

Class II Drugs Event

Event ID:
89869

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/17/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/30/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurolife Pharma, LLC
2400 US Highway 130
Dayton NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Glycopyrrolate Tablets, USP, 1 mg, 100-count bottle, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, NDC 13107-014-01.

Product Quantity:
4080 bottles

Reason for Recall:
Presence of Foreign Substance: Complaint for pieces of glass discovered in a sealed bottle which came from equipment within the packaging room.

Recall Number:
D-0736-2022

Code Information:
Lot: 01421008A1, Exp 03/2023

Class II Drugs Event

Event ID:
89871

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/23/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/31/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lansoprazole Delayed-Release Capsules, USP, 15 mg, a) 30-count bottle, (NDC 55111-398-30), b) 90-count bottle, (55111-398-90), Rx Only, Manufactured. By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090, India

Product Quantity:
8,352 bottles (30-count), 1,368 bottles (90-count)

Reason for Recall:
Failed Dissolution Specifications; during long term stability testing.

Recall Number:
D-0737-2022

Code Information:
Lot # a) C2103093, Exp. 12/2023; b)C2103092, Exp. 12/2023.

Product Description:
Lansoprazole Delayed-Release Capsules, USP, 30 mg, 90-count bottle, Rx Only, Manufactured By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090, India, NDC 55111-399-90.

Product Quantity:
7,703 bottles

Reason for Recall:
Failed Dissolution Specifications; during long term stability testing.

Recall Number:
D-0738-2022

Code Information:
Lot# C2102911, Exp. 12/2023

Class III Drugs Event

Event ID:
89678

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Product was distributed to one retail consignee in NY.

Associated Products

Product Description:
Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05%,15 g tubes, Rx only, Manufactured by: Taro Pharmaceuticals Industries Ltd. Haifa Bay, Israel 2624761, Distributed by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532, NDC 51672-4048-1

Product Quantity:
768 tubes

Reason for Recall:
Failed Content Uniformity Specifications: Out-of-specification result for the Betamethasone Dipropionate assay of a stability sample

Recall Number:
D-0727-2022

Code Information:
Lot #: AC33883, Exp. Date June 2023

Class III Drugs Event

Event ID:
89833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/16/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Atorvstatin Calcium Tablets, USP 80 mg*, 90 Tablets, Rx Only, Mrd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409, INDIA, NDC 55111-124-90

Product Quantity:
28,068 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification results for related substance.

Recall Number:
D-0726-2022

Code Information:
Lot: T000707, T000756, T000758, T000759, Exp 03/2022; T2100600, T2101075, Exp. 1/2023; T2102802, Exp. 07/2023

Not Yet Classified Drugs Event

Event ID:
89854

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
03/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Product was distributed in Arkansas, Florida, North Carolina, South Carolina and Ohio.

Associated Products

Product Description:
Meclizine Hydrochloride Tablets USP, 12.5 mg, packaged in a case of 24 bottles (100-count bottle), Rx only, Manufactured by: Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD, NDC 59746-122-06

Product Quantity:
12,174 bottles

Reason for Recall:
Labeling: Label mix-up: Incorrect label placed on product. Shipper box labeled meclizine contained bottles labeled prednisone and actually contained meclizine

Recall Number:

Code Information:
Lot # 22P0036, Exp 12/2024