Enforcement Report - Week of April 5, 2023

Class II Drugs Event

Event ID:
91674

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2023

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Apollo Care
3801 Mojave Ct Ste 101
Columbia MO United States

Distribution Pattern:
MO

Associated Products

Product Description:
Fentanyl 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (1mg/mL) added to 250mL 0.9% Sodium Chloride, For Epidural Use Only, Rx only, 3801 Mojave Ct. Suite 101, Columbia, MO 65202, NDC 71170-950-25

Product Quantity:
215 bags

Reason for Recall:
Lack of assurance of sterility: Suspected microbial growth present on external label packaging.

Recall Number:
D-0487-2023

Code Information:
Lot #: AC-016581

Class II Drugs Event

Event ID:
91802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2023

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

Recalling Firm:
Endo Pharmaceuticals, Inc.
1400 Atwater Dr
Malvern PA United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Calcitonin Salmon Nasal Spray, USP, 2200 International Units per mL corresponding to 200 International Units/spray, 3.7 mL bottle, Rx only, Manufactured by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 49884-161-11.

Product Quantity:
372,938 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications and Subpotent Drug: High Out of Specification results for a known and unknown impurity as well as low Out of Specification results for assay.

Recall Number:
D-0475-2023

Code Information:
Lot #: 34770301, exp. date Mar-23; 34770401, exp. date May-23; 12981201, exp. date Nov-23; 13037201, exp. date Dec-23; 13037301, 13647801, exp. date Feb-24; 13722101, exp. date Mar-24; 13980101, 13980001, exp. date Apr-24; 14461701, 14461801, exp. date Jul-24; 14706201, exp. date Aug-24; 14935601, exp. date Oct-24; 5500131A, 5500132A, exp. date Mar-25

Class II Drugs Event

Event ID:
91921

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Montelukast Sodium Tablets, USP, 10 mg Tablets, Rx Only, Packaged as: a) 30-count bottle, NDC 61919-0009-30; b) 90-count bottle, NDC 61919-0009-90; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
90 count: 495 bottles; 30 count: 13 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0476-2023

Code Information:
a) [30 count bottles] Lot, expiry: 20JU2211, exp 5/31/2024; b) [90 count bottles] Lot, expiry: 25JU2128 , exp 12/31/2023; 13SE2132 , exp 12/31/2023; 25JU2133 , exp 12/31/2023; 16JU2127 , exp 12/31/2023; 18MY2126 , exp 12/31/2023; 10JU2111 , exp 12/31/2023; 14SE2111 , exp 1/31/2024 ; 14JY2115 , exp 1/31/2024 ; 25OC2113 , exp 2/29/2024 ; 21SE2227 , exp 2/29/2024 ; 10DE2123 , exp 3/31/2024 ; 22NO2115 , exp 3/31/2024 ; 21JA2202 , exp 4/30/2024 ; 29DE2110 , exp 4/30/2024 ; 28FE2227 , exp 4/30/2024 ; 06JU2208 , exp 5/31/2024 ; 30MA2229 , exp 5/31/2024 ; 30AU2216 , exp 6/30/2024 ; 23NO2203 , exp 6/30/2024 ; 14DE2216 , exp 7/31/2025 ; 12JA2305 , exp 7/31/2025 .

Product Description:
Finasteride, USP, 5 mg Tablets, Rx Only, Packaged as a 90-count bottle, NDC 61919-0733-90; Packaged and Distributed By: Direct Rx

Product Quantity:
19 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0477-2023

Code Information:
Lot, expiry: 19AU2205, exp 12/31/24; 12OC2211, exp 12/31/24

Product Description:
Ropinirole, USP, 0.25 mg Tablets, Rx Only, Packaged as a 30-count bottle, NDC 72189-0364-30; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
9 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0478-2023

Code Information:
Lot, expiry: 21JU2210, exp 7/31/23

Product Description:
Ropinirole, USP, 1 mg Tablets, Rx Only, Packaged as a 30-count bottle, NDC 72189-0364-30; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
4 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0479-2023

Code Information:
Lot, expiry: 22JU2216 , exp 8/31/23

Product Description:
Glimepiride, USP, 1 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0723-30; b) 90-count bottle, NDC 61919-0723-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
30 count: 4 bottles; 90 count: 172 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0480-2023

Code Information:
a) [30 count bottles] Lot, expiry: 07MA2208, exp 5/31/2024 b) [90 count bottles] Lot, expiry: 09AU2128 , exp 1/31/2024; 28JY2102 , exp 1/31/2024; 06AU2103 , exp 1/31/2024 ; 03JA2210 , exp 1/31/2024 ; 14JY2114 , exp 1/31/2024 ; 05NO2106 , exp 2/29/2024 ; 13OC2118 , exp 2/29/2024 ; 08DE2121 , exp 2/29/2024 ;

Product Description:
Glimepiride, USP, 2 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0488-30; b) 90-count bottle, NDC 61919-0448-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
30 count: 12 bottles; 90 count: 253 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0481-2023

Code Information:
a) [30 count bottles] Lot, expiry: 21JU2112 , exp 9/30/2023 b) [90 count bottles] Lot, expiry: 22DE2113 , exp 1/31/2024; 27JA2235 , exp 3/31/2024; 05AP2224 , exp 7/31/2024 ; 06AU2104 , exp 1/31/2024 ; 08JU2215 , exp 9/30/2024 ; 209AU2109 , exp 1/31/2024 ; 15JU2113 , exp 9/30/2023 ; 21FE2217 , exp 4/30/2024 ; 21OC2115 , exp 2/29/2024 ; 23JY2144 , exp 1/31/2024 ; 25JU2124 , exp 9/30/2023 ; 29AP2219 , exp 7/31/2024 ; 07DE2128 , exp 3/31/2024 .

Product Description:
Glimepiride, USP, 4 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0250-30; b) 90-count bottle, NDC 61919-0250-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
30 count: 7 bottles; 90 count: 395 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0482-2023

Code Information:
a) [30 count bottles] Lot, expiry: 13DE2111 , exp 3/31/2024 b) [90 count bottles] Lot, expiry: 17NO2116 , exp 1/31/2024 ; 27JA2234 , exp 4/30/2024; 02MA2218, exp 6/30/2024 ; 12MY2211, exp 7/31/2024 ; 13JY2107, exp 10/31/2023; 15AP2221 , exp 7/31/2024 ; 17AU2110 , exp 10/31/2023; 20SE2108 , exp 10/31/2023; 23JU2115 , exp 10/31/2023; 28JY2101 ,exp 10/31/2023; 30JY2101 ,exp 10/31/2023; 05JA2212 , exp 3/31/2024 ; 13DE2130 , exp 3/31/2024 ; 21OC2111, exp 1/31/2024 ; 17NO2116 , exp 3/31/2024 .

Product Description:
Simvastatin, USP, 5 mg Tablets, Rx Only, Packaged as a 90-count bottle, NDC 61919-0710-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
51 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0483-2023

Code Information:
Lot, expiry: 03JA2209, 28FE2225, 28AP2211, 07AP2203, exp 6/30/23

Product Description:
Simvastatin, USP, 10 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0688-30 b) 90-count bottle, NDC61919-0688-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
30 count: 6 bottles; 90 count: 106 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0484-2023

Code Information:
a) [30-count bottles] Lot, expiry: 05AU2206, exp 10/31/23; b) [90-count bottles] Lot, expiry: 30MA2213, exp 6/30/23; 10DE2124, exp 3/31/23; 15MA2224, exp 5/32/23; 27JA2229, exp 3/31/23.

Product Description:
Simvastatin, USP, 20 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0446-30 b) 90-count bottle, NDC 61919-0446-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
30 count: 5 bottles; 90 count: 53 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0485-2023

Code Information:
a) [30-count bottles] Lot, expiry: 09JA2312 , exp 2/28/2025; b) [90-count bottles] Lot, expiry: 22OC2111, exp 1/31/2023; 13OC2120, exp 3/31/2023; 16JY2104, exp 12/31/2023; 09AU2125 , exp 1/31/2024 ; 28JY2125 , exp 1/31/2024 ; 23SE2115 , exp 3/31/2024 ; 23SE2115 , exp 3/31/2024 ; 07JA2211 , exp 5/31/2024 ; 27JA2214 , exp 5/31/2024 ; 15AP2224 , exp 6/30/2024 ; 24MA2221 , exp 6/30/2024 ; 16AU2214 , exp 6/30/2024 .

Product Description:
Simvastatin, USP, 40 mg, Rx Only, Packaged as a 90-count bottle, NDC 61919-0431-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534

Product Quantity:
269 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0486-2023

Code Information:
Lot, expiry: 28AP2212 , exp 7/31/2024 ; 24MA2230, exp 7/31/2024; 11JA2203 , exp 3/31/2023; 02FE2217 , exp 2/28/2023; 10DE2126 , exp 2/28/2023; 25MA2201, exp 5/31/2023; 28FE2230, exp 5/31/2023.

Not Yet Classified Drugs Event

Event ID:
91880

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/14/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories, LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Dabigatran Etexilate Capsules, 75 mg, Rx Only, 60 Capsules per bottle, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-474-60.

Product Quantity:
13,560 bottles

Reason for Recall:
CGMP Deviations: Testing results Out-Of-Specification for nitrosamine impurity.

Recall Number:

Code Information:
Lot #s: 22142462, 22142463, 22142464, Exp 5/2024; 22143000, 22143001, 22143002, Exp 6/2024.

Product Description:
Dabigatran Etexilate 150mg Capsules, 150 mg, Rx Only, 60 Capsules per bottle, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC 67877-475-60.

Product Quantity:
12,804 bottles

Reason for Recall:
CGMP Deviations: Testing results Out-Of-Specification for nitrosamine impurity.

Recall Number:

Code Information:
Lot #s: 22142448, 22142449, 22142450, Exp 5/2024; 22143845, Exp 7/2024.