Enforcement Report - Week of September 5, 2018

Class II Drugs Event

Event ID:
80699

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pharmcore Inc.
1109 E Hallandale Beach Blvd
Hallandale Beach FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Human Chorionic Gonadotropin 5000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
5718 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1147-2018

Code Information:
Lots: HCG50319 Exp. 4/30/2019; HCG50316 Exp. 3/31/2019; HCG50317 Exp. 4/30/2019; HCG50315 Exp. 3/31/2019; HCG50318 Exp. 4/30/2019; HCG50320 Exp. 4/30/2019; HCG50321 Exp. 4/30/2019; HCG50311 Exp. 3/31/2019; HCG50310 Exp. 3/31/2019; HCG50309 Exp. 3/31/2019; HCG50313 Exp. 3/31/2019; HCG50314 Exp. 3/31/2019;

Product Description:
Human Chorionic Gonadotropin 11000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
864 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1148-2018

Code Information:
Lots: HCG1116 Exp. 3/31/2019; HCG1117 Exp. 4/30/2019

Product Description:
Human Chorionic Gonadotropin 20000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
355 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1149-2018

Code Information:
Lots: HCG22038 Exp. 3/31/2019; HCG22039 Exp. 4/30/2019

Product Description:
Human Chorionic Gonadotropin 2500 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
3070 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1150-2018

Code Information:
Lots: HCG25112 Exp. 2/28/2019; HCG25110 Exp. 1/31/2019; HCG25115 Exp. 4/30/2019; HCG25114 Exp. 4/30/2019; HCG25111 Exp. 2/28/2019

Product Description:
Human Chorionic Gonadotropin 4000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
2085 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1151-2018

Code Information:
Lots: HCG40160 Exp. 2/28/2019; HCG40161 Exp. 4/30/2019; HCG40159 Exp. 2/28/2019; HCG40162 Exp. 4/30/2019; HCG50308 Exp. 2/28/2019

Product Description:
Human Chorionic Gonadotropin 6000 IU Vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
3351 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1152-2018

Code Information:
Lots: HCG60122 Exp. 4/30/2019; HCG60124 Exp. 6/30/2019; HCG60121 Exp. 4/30/2019; HCG60123 Exp. 5/31/2019; HCG60120 Exp. 4/30/2019; HCG60118 Exp. 2/28/2019; HCG1115 Exp. 1/31/2019

Product Description:
Ipamorelin 3 mg Lyophilized 1 vial 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
6 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1153-2018

Code Information:
Lot: IPA3-17 Exp. 07/2018

Product Description:
Methylcobalamin 10 mg vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
1115 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1154-2018

Code Information:
Lots: MTLY-19 Exp. 10/31/2018; MTLY-18 Exp. 8/31/2018

Product Description:
Ipamorelin 9 mg vial Lyophilized 1109 East Hallandale Beach Blvd. Hallandale Beach, FL 33009

Product Quantity:
599 vials

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-1155-2018

Code Information:
Lots: IPA9-15 Exp. 3/31/2019; IPA9-14 Exp. 1/31/2019

Class II Drugs Event

Event ID:
80791

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Doxycycline Hyclate USP Tablets, 100 mg packaged in a) 2-count bottles, NDC 55289-866-02; b) 6-count bottles, NDC 55289-866-06; c) 7-count bottles, NDC 55289-866-07; d) 10-count bottles, NDC 55289-866-10; e) 14-count bottles, NDC 55289-866-14; f) 20-count bottles, NDC 55289-866-20; g) 28-count bottles, NDC 55289-866-28; h) 30-count bottles, NDC 55289-866-30; i) 120-count bottles, NDC 55289-866-98; j) 300-count bottles, NDC 55289-866-87; k) 400-count bottles, NDC 55289-866-74; Rx only, Packaged By PD-Rx Pharmaceuticals, Oklahoma City, OK 73127.

Product Quantity:
6,641 bottles

Reason for Recall:
Failed Dissolution Specifications: manufacturer West-Ward Pharm Corp. recalled these repackaged lots due to failed dissolution results.

Recall Number:
D-1127-2018

Code Information:
Lot #: a) D17D29, L17C73, F18E73, Exp. 1/31/19; b) H17D70, K17F66, G18F26, Exp. 1/31/19; c) C18G26, F18E36, Exp. 1/31/19; d) F18A85, Exp. 1/31/19; e) K17B44, K17E29, L17D93, Exp. 1/31/19; E17B88, Exp. 5/31/19; H17A52, H17D67, Exp. 7/31/19; f) E17B01, E17E83, Exp. 5/31/19; F17C99, Exp. 6/30/19; G17C08, G17E18, H17B01, H17B66, H17F67, I17A56, Exp. 7/31/19; g) E17E27, Exp. 1/31/19, I17A33, G17D62, Exp. 7/31/19; h) E17B35, E17D90, Exp. 5/31/19, F17C13, Exp. 6/30/19, G17B25, H17C58, Exp. 7/31/19; i) G17D59, Exp. 7/31/19; j) I17A69, G17D58, Exp. 7/31/19; k) G17D56, Exp. 7/31/19.

Class II Drugs Event

Event ID:
80828

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Valsartan Tablets, USP 40 mg Rx Only NDC 50268-783-15 50 Tablets (5x10) Unit Dose Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
6776 cartons (338,800 tablets)

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1130-2018

Code Information:
Lots: 18491 Exp. 10/2018; 19531 Exp. 04/2019; 20168 Exp. 05/2019; 20671 Exp. 08/2019; 21049 Exp. 10/2019; 21635 Exp. 10/2019

Product Description:
Valsartan Tablets, USP 80 mg Rx Only 50 Tablets (5x10) Unit Dose NDC 50268-784-15 Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
728 cartons (36,400 tablets)

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1131-2018

Code Information:
Lots: 18492 Exp. 11/2018; 20169 Exp. 05/2019

Product Description:
Valsartan Tablets, USP 160 mg Rx Only 50 Tablets (5x10) Unit Dose NDC 50268-785-15 Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
818 cartons (40,900 tablets)

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1132-2018

Code Information:
Lots: 17717 Exp. 07/2018; 18493 Exp. 01/2019; 19761 Exp. 04/2019

Product Description:
Valsartan Tablets, USP 320 mg Rx Only 30 Tablets (6x5) Unit Dose NDC 50268-786-13 Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Product Quantity:
1496 cartons (44,880 tablets)

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1133-2018

Code Information:
Lots: 17718 Exp. 07/2018; 18700 Exp. 01/2019; 19133 Exp. 02/2019; 19532 Exp. 04/2019

Class II Drugs Event

Event ID:
80847

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Valsartan Tablets USP, 80mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-068-90

Product Quantity:
24468 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1134-2018

Code Information:
Batch: BV46C007, BV46C008, BV46C009, BV46C010, BV46C011, BV46C012, BV46C003, BV46C006

Product Description:
Valsartan Tablets USP, 160mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-069-90

Product Quantity:
14016 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1135-2018

Code Information:
Batch: BV47C005, BV47C006, BV47D001, BV47C003, BV47C004

Product Description:
Valsartan Tablets USP, 320mg, 90 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-070-90

Product Quantity:
ALL

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1136-2018

Code Information:
Batch: BV48D001, BV48D002

Product Description:
Amlodipine and Valsartan Tablets, USP, 10 mg/320 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-204-30

Product Quantity:
89616 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1137-2018

Code Information:
Batch: BV77D013, BV77C011, BV77D001, BV77D002, BV77D003, BV77D004, BV77D005, BV77D006, BV77D007, BV77D008, BV77D009 , BV77D010, BV77D011, BV77D012, BV77C009, BV77C010

Product Description:
Amlodipine and Valsartan Tablets, USP, 5 mg/320 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-205-30

Product Quantity:
66864 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1138-2018

Code Information:
Batch: BV84D010, BV84E001, BV84C011, BV84D001, BV84D002, BV84D005, BV84D006, BV84D007, BV84D008, BV84D009, BV84C006, BV84C007, BV84C008, BV84C009

Product Description:
Amlodipine and Valsartan Tablets, USP, 10 mg/160mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-206-30

Product Quantity:
46272 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1139-2018

Code Information:
Batch: BV65D002, BV65C002, BV65C003, BV65C004, BV65D001

Product Description:
Amlodipine and Valsartan Tablets, USP, 5 mg/160 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-207-30

Product Quantity:
78144 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1140-2018

Code Information:
Batch: BV53D004, BV53C006, BV53D001, BV53D002, BV53D003, BV53C004, BV53C005

Product Description:
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 10 mg/320 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-325-30

Product Quantity:
169,200 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1141-2018

Code Information:
Batch: BBX2D025, BBX2D026, BBX2E001, BBX2E002, BBX2E003, BBX2E004, BBX2E005, BBX2D003, BBX2D004, BBX2D005, BBX2D006, BBX2D007, BBX2D008, BBX2D015, BBX2D016, BBX2D017, BBX2D018, BBX2D019, BBX2D020, BBX2D021, BBX2D022, BBX2D023, BBX2D024, BBX2D001, BBX2D002, BBX2D009, BBX2D010, BBX2D011, BBX2D012, BBX2D013, BBX2D014, BBX2C007

Product Description:
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 5 mg/160 mg/12.5 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-326-30

Product Quantity:
50,784 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1142-2018

Code Information:
Batch: BBY1E001, BBY1E003, BBY1C002, BBY1E002, BBY1D001

Product Description:
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 10 mg/160 mg/12.5 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-327-30

Product Quantity:
22704 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1143-2018

Code Information:
Batch: BBY2E001, BBY2D001, BBY2D002

Product Description:
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 10 mg/160 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-328-30

Product Quantity:
34320 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1144-2018

Code Information:
Batch: BBX9D004, BBX9E001, BBX9D001, BBX9D002, BBX9D003

Product Description:
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP, 5 mg/160 mg/25 mg, 30 tablets per bottle, Rx Only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. NDC: 13668-329-30

Product Quantity:
37704 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1145-2018

Code Information:
Batch: BBY4D004, BBY4E001, BBY4D001, BBY4D002, BBY4D003

Class II Drugs Event

Event ID:
80876

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/30/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Global Supply
One Burtt Road
Andover MA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Children s Advil Suspension Ibuprofen Oral Suspension, 100 mg per 5mL, 4 FL OZ (120 ml) bottle, Pfizer, Madison, NJ 07940 USA, NDC 0573-0207-30, UPC 3-0573-0207-30-0

Product Quantity:
17,136 bottles

Reason for Recall:
Labeling Error: Not elsewhere classified. product has a dosage cup marked in teaspoons and the instructions on the label are described in milliliters.

Recall Number:
D-1169-2018

Code Information:
Lot #: R51129, Exp. 11/20

Class II Drugs Event

Event ID:
80881

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/21/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
TX and MS only

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP 100 mL bags, Rx only, Baxter Healthcare Corporation Deerfield, IL 60015 USA, NDC 0338-0049-18

Product Quantity:
33600 bags

Reason for Recall:
CGMP Deviations

Recall Number:
D-1128-2018

Code Information:
Lot #: P380287, Exp. date 12/2019

Class II Drugs Event

Event ID:
80890

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/21/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/29/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Auro Pharmacies, Inc.
520 W La Habra Blvd
La Habra CA United States

Distribution Pattern:
Nationwide in USA

Associated Products

Product Description:
CoEnzyme-Q10 injectable, 20 mg/mL, 10 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
39 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1156-2018

Code Information:
Lot #: 180626/3, Exp 25-Aug-18

Product Description:
Calcium Gluconate injectable, 10%, 50 ml Single Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
167 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1157-2018

Code Information:
Lot #: 180626/10, Exp 24-Sep-18

Product Description:
Dexpanthenol injectable, 250 mg/mL, 10 mL Single Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
91 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1158-2018

Code Information:
Lot #: 180529/2, Exp 27-Aug-18 and 180620/11, Exp 18-Sep-18

Product Description:
Glutathione injectable, 200 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
183 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1159-2018

Code Information:
Lot #: 180716/21, Exp 14-Oct-18

Product Description:
Methyl-Cobalamin injectable, 1 mg/mL, packaged in a) 5 mL and b) 30 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
114 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1160-2018

Code Information:
Lot #: a) 180618/2, Exp 16-Sep-18; b) 180618/2, Exp 16-Sep-18

Product Description:
Methyl-Cobalamin injectable, 5 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
90 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1161-2018

Code Information:
Lot #: 180618/3, Exp 16-Sep-18

Product Description:
Methyl-Cobalamin injectable, 10 mg/mL, 30 mL Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
81 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1162-2018

Code Information:
Lot #: 180702/1, Exp 30-Sep-18

Product Description:
Testosterone Cypionate/Enanthate injectable, 126/54 mg/mL, packaged in a) 3 mL and b) 5 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
43 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1163-2018

Code Information:
Lot #: 180709/21, Exp 07-Sep-18

Product Description:
Testosterone Cypionate/Enanthate injectable, 200/50 mg/mL, packaged in a) 5 mL and 8 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
32 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1164-2018

Code Information:
Lot #: 180606/18, Exp 30-Nov-18

Product Description:
Testosterone Enanthate/Cypionate injectable, 126/54 mg/mL, packaged in a) 3 mL and b) 5 mL Multiple Dose vials, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
11 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1165-2018

Code Information:
Lot #: 180709/24, Exp 07-Sep-18

Product Description:
Folic Acid injectable, 10 mg/ml, 30 ml Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
40 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1166-2018

Code Information:
Lot #: 180611/1, Exp 09-Sep-18

Product Description:
Methyl-Cobalamin injectable, 2 mg/mL, 30 ml Multiple Dose vial, Rx only, Central Drugs Compounding Pharmacy, 520 W. La Habra Blvd, La Habra, CA 90631

Product Quantity:
74 vials

Reason for Recall:
Lack of Assurance of Sterility: Inadequate processes and equipment to assure the sterility of products intended to be sterile.

Recall Number:
D-1167-2018

Code Information:
Lot #: 180620/2, Exp 18-Sep-18

Class II Drugs Event

Event ID:
80891

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/28/2018

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
South Carolina

Associated Products

Product Description:
Amlodipine/Valsartan/HCTZ 10mg/320mg/25mg Tablet, Rx Only (HDPE 90cc Bottles in cardboard trays) MFG Torrent Pharma LTD, Indrad, India 38272, NDC #70518-1220-0

Product Quantity:
3 bottles of 90 tablets (270 tablets overall)

Reason for Recall:
CGMP Deviations: Detection of trace amounts of NDMA, a possible impurity or contaminant in an active pharmaceutical ingredient.

Recall Number:
D-1146-2018

Code Information:
70518-1220-0; Lot #: B0476653-080218; Exp. Date: 08/2019

Class III Drugs Event

Event ID:
80767

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/29/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Azelastine HCl Ophthalmic Solution 0.05%, 6 mL in 10 mL HDPE bottle, 1 bottle per box, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-718-10

Product Quantity:
8,574 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:out-of-specification (OOS) results for Azelastine N-oxide

Recall Number:
D-1168-2018

Code Information:
Lot# 6K89A, 6K90A, 6K92A, exp 9/18

Class III Drugs Event

Event ID:
80833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/21/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mayne Pharma Inc
1240 Sugg Pkwy
Greenville NC United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Oxycodone and Acetaminophen Tablets, USP, 5 mg*/325 mg, 100-count bottle, Rx Only, Manufactured by: Mayne Pharma, Greenville, NC 27834, NDC 68308-841-01.

Product Quantity:
6456 bottles

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Lot FG10517 is mislabeled on the primary container with Lot FG01517, shipper labels and invoices contain the correct lot number of FG10517.

Recall Number:
D-1129-2018

Code Information:
Lot: FG01517, Exp. 12/31/2019

Not Yet Classified Drugs Event

Event ID:
80814

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Living Well Remedies, LLC
967 Scioto Dr
Franklin Lakes NJ United States

Distribution Pattern:
United States

Associated Products

Product Description:
Living Well Remedies Weight Away Remedy, 2 fl oz (59 mL) Distributed by Living Well Remedies, LLC P.O. Box 704, Franklin Lakes, NJ 07417 www.LivingWellRemedies.com. Made in the USA

Product Quantity:
128 (2 fl oz spray bottles)

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Weight Away Remedy is being recall due to out of specification microbial results.

Recall Number:

Code Information:
Lot #: 111417LWL614, Exp date 11/14/19