Enforcement Report - Week of March 27, 2019

Class II Drugs Event

Event ID:
81943

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/16/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rx Pak Division of McKesson Corporation
4971 Southridge Blvd Ste 111-115
Memphis TN United States

Distribution Pattern:
Product was distributed to 5 major distributors who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Docusate Sodium, 100mg softgels, packaged in 10 x 10 unit dose blister cards, For institutional use only, Mfg by: Aenova Holding GmBh, Miami, Fl 33186, NDC 63739-0478-10

Product Quantity:
29,622 Blister Cards

Reason for Recall:
Labeling: Label mix-up: Secondary carton may be labeled as Gabapentin 300mg instead of Docusate Sodium 100mg softgel caps.

Recall Number:
D-1007-2019

Code Information:
Lot # 0119397, Exp 02/2020

Class II Drugs Event

Event ID:
81946

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/20/2019

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 USA and Puerto Rico

Associated Products

Product Description:
Alprazolam Tablets, USP, 0.25 mg, 10x10 per carton, Rx Only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-788-20

Product Quantity:
10,281 UD cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Elevated levels of a known impurity detected during 6-month RT stability interval.

Recall Number:
D-1013-2019

Code Information:
Lots: 3095198, 3096266, 3098776, EXP 05-2019

Class II Drugs Event

Event ID:
82114

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/31/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

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:
Product was distributed to major distribution chains throughout the United States.

Associated Products

Product Description:
Valsartan Tablets USP 320 mg, 90 count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ --- NDC 65862-573-90

Product Quantity:

Reason for Recall:
GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.

Recall Number:
D-1035-2019

Code Information:
Lot Numbers: 473180004A, 473180005A, exp. date Feb 2020; 473180006A, exp. date Mar 2020; 473180016A, 473180017A, exp. date May 2020; 473170019A, exp. date Oct 2019

Product Description:
Amlodipine and Valsartan Tablets USP 10mg/160mg, 30 count bottles, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ Manufactured by: Aurobindo Pharma Limited, India --- NDC 65862-739-30

Product Quantity:

Reason for Recall:
GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.

Recall Number:
D-1036-2019

Code Information:
Lot Numbers: VFSA17007-A, exp. date Oct-2019

Product Description:
Valsartan Tablets USP 40 mg, 30 count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ --- NDC 65862-570-30

Product Quantity:

Reason for Recall:
GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.

Recall Number:
D-1037-2019

Code Information:
Lot Numbers: 470180008A, exp. date Feb 2020; 470180014A, 470180016A, exp. date Mar 2020; 470180032A, exp. date May 2020

Product Description:
Valsartan Tablets USP 80 mg, 90 count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ --- NDC 65862-571-90

Product Quantity:

Reason for Recall:
GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.

Recall Number:
D-1038-2019

Code Information:
Lot Numbers: 471170015A, exp. date Sep 2019; 471180004A, 471180005A, exp. date Feb 2019

Product Description:
Valsartan Tablets USP 160 mg, 90 count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ --- NDC 65862-572-90

Product Quantity:

Reason for Recall:
GCMP Deviations: FDA analysis confirmed presence of trace amounts of an impurity, N-nitrosodiethylamine (NDEA) found in the API used to manufacture the product.

Recall Number:
D-1039-2019

Code Information:
Lot Numbers: 472180001A, 472180002A, 472180003A, 472180004A, exp. date Jan 2020; 472180007A, 472180008A, 472180009A, 472180010A, exp. date Mar 2020; 472180013A, 472180014A, exp. date Apr 2020

Class II Drugs Event

Event ID:
82147

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/21/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
NJ, NY, FL

Associated Products

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP 100 mg/25 mg, 90 count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, India. NDC 33342-0052-10

Product Quantity:
9695 bottles

Reason for Recall:
CGMP Deviation: Presence of NDEA (N-Nitrosodimethylamine), a carcinogen impurity, detected in the active ingredient.

Recall Number:
D-1040-2019

Code Information:
Lot BLM715A, Jul-19

Class II Drugs Event

Event ID:
82281

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Camber Pharmaceuticals Inc
1031 Centennial Ave
Piscataway NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Losartan Potassium Tablets USP, 25 mg, Rx only, a) 90 count (NDC 31722-700-90), b) 500 count (NDC 31722-700-05) and c) 1000 count (NDC 31722-700-05) bottles, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar -509 301, India

Product Quantity:
351,732 bottles

Reason for Recall:
CGMP Deviations; trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) detected in the active pharmaceutical ingredient

Recall Number:
D-1041-2019

Code Information:
a) LOP17026B, LOP17050, LOP1705, LOP17052, LOP17053, Exp. Sep-19; LOP17061, Exp. Oct-19; LOP18035, LOP18036, Exp. Dec-19; b) LOP17026, Exp. Sep-19; c) LOP17006, Exp. May-19, LOP17025, Exp. Sep-19, LOP17068, Exp, Oct-19, LOP18037, LOP18038, LOP18039, Exp. Dec-19, LOP18057, Exp. Jan-20

Product Description:
Losartan Potassium Tablets USP, 50 mg, Rx only, a) 30 count (NDC 31722-701-30), b) 90 count (NDC 31722-701-90), c) 1000 count (NDC 31722-701-10) bottles, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar -509 301, India

Product Quantity:
69712 bottles

Reason for Recall:
CGMP Deviations; trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) detected in the active pharmaceutical ingredient

Recall Number:
D-1042-2019

Code Information:
a) LOP17028C, Exp. Sep-19, LOP17064A, Exp. Nov-19; b) LOP17027, Exp Sep-19, LOP17063, LOP17093, Exp. Nov-19; LOP17094, LOP17095, LOP17097A, LOP17105, LOP17107, Exp. Dec-19; c) LOP17004, Exp Dec-19, LOP17028B, Exp Sep-19, LOP17048, LOP17049 Exp Oct-19, LOP17056, LOP17073, LOP17074, LOP17076 Exp Nov-19, LOP17096, Exp Dec-19, LOP18077A, LOP18078, LOP18079, LOP18080 Exp Feb-20; LOP18081, LOP18084, LOP18095, LOP18096 Exp Mar-20

Product Description:
Losartan Potassium Tablets USP, 100 mg, Rx only, a) 30 count (NDC 31722-702-30), b) 90 count (NDC 31722-702-30), c) 1000 count (NDC 31722-702-10) bottles, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar -509 301, India

Product Quantity:
683,641 bottles

Reason for Recall:
CGMP Deviations; trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) detected in the active pharmaceutical ingredient

Recall Number:
D-1043-2019

Code Information:
a) LOP17011, Exp Aug-19, Lot LOP17087 Exp Nov-19; b) LOP17012, LOP17013, Exp Aug-19, LOP17042, LOP17043 Exp Oct-19, LOP17044, LOP17045, Exp Nov-19, LOP18024, LOP18025, LOP18026, LOP18027, LOP18028, LOP18029, LOP18030, Exp. Dec-19; c) LOP17005, Exp May-19, LOP17014, Exp Aug-19, LOP17016, LOP17023, Exp Sep-19, LOP17083, Exp Oct-19, LOP17084, LOP17085, LOP17086, Exp Nov-19, LOP18021, LOP18022, LOP18023, LOP18031, LOP18032, LOP18033, LOP18050, LOP18051, Exp Dec-19, LOP18109, LOP18111, Exp Mar-20, LOP18122, LOP18123, LOP18124, LOP18125, LOP18126, LOP18127, LOP18128, LOP18129, LOP18130, LOP18131C, LOP18133, Exp Jun-20

Class II Drugs Event

Event ID:
82314

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/05/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Losartan Potassium Tablets USP 50 mg 50 Tablets (5x10) Unit Dose boxes, Rx Only, Manufactured for: AvKARE Inc. Pulaski, TN 38478 ---- NDC 50268-517-15

Product Quantity:

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified

Recall Number:
D-1044-2019

Code Information:
Lots: 20961 Exp. 09/2019; 20477 Exp. 08/2019

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP 50 mg/12.5 mg 50 Tablets (5x10) Unit Dose boxes, Rx Only Manufactured for: AvKARE Inc. Pulaski, TN 38478 --- NDC 50268-513-15

Product Quantity:

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified

Recall Number:
D-1045-2019

Code Information:
Lot: 19454 Exp. 04/30/2019

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP 100 mg/12.5 mg 50 Tablets (5x10) Unit Dose boxes, Rx Only Manufactured for: AvKARE Inc. Pulaski, TN 38478 --- NDC 50268-514-15

Product Quantity:

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified

Recall Number:
D-1046-2019

Code Information:
Lot: 19326 Exp. 03/31/2019

Class II Drugs Event

Event ID:
82316

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Valsartan Tablets USP 160 mg, 100 Tablets (10 x 10) per Unit Dose Blisters, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217 (Individual Dose NDC:60687-139-11, Carton NDC#: 60687-139-01)

Product Quantity:
3337 cartons

Reason for Recall:
CGMP Deviation: Presence of NDEA (N-Nitrosodimethylamine), a carcinogen impurity, detected in the active ingredient.

Recall Number:
D-1047-2019

Code Information:
Lot 179791, Mar 2020

Class II Drugs Event

Event ID:
82326

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Legacy Pharmaceutical Packaging LLC
13333 Lakefront Dr
Earth City MO United States

Distribution Pattern:
Wal-Mart distribution centers in AR, CA, GA, IN and MD

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 25 mg, 30 tablet bottles, Rx Only, Distributed by: Wal-Mart, Bentonville, AR 72716, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045 NDC 68645-577-54

Product Quantity:
456,732 bottles

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) detected

Recall Number:
D-1048-2019

Code Information:
Lots: 180952, exp Oct-19, 180953, exp Dec-19, 181086, exp Sep-19, 181572, exp Jan-20

Product Description:
Losartan Potassium Tablets, USP, 50 mg, 30 tablet bottles, Rx Only, Distributed by: Wal-Mart, Bentonville, AR 72716, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045. NDC 68645-578-54

Product Quantity:
2,851,284 bottles

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) detected

Recall Number:
D-1049-2019

Code Information:
Lots: 180921, exp Sep-19, 180922, exp Oct-19, 180923, 180924, 181118, exp Nov-19, 181119, exp Oct-19, 181407, exp Nov-19, 181408, exp Dec-19, 181573, 181725, 181726, exp Feb-20, 181948, exp Mar-20, 181960, exp Feb-20, 182385, 182386, 182387, exp Mar-20

Product Description:
Losartan Potassium Tablets, USP, 100 mg, 30 tablet bottles, Rx Only, Distributed by: Wal-Mart, Bentonville, AR 72716, Manufactured for: Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045. NDC 68645-579-54

Product Quantity:
2,497,856 bottles

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) detected

Recall Number:
D-1050-2019

Code Information:
180886, Nov-19; 180887, 180888, 180905, Dec-19; 181123, Sep-2019; 181124, Oct-2019, 181125, Aug-19, 181351, Nov-19, 181352, Dec-19, 181551, Nov-19, 181628, 181629, 181727, 181728, Jun-20; 181890, Mar-20; 181891, 181897, Jun-20; 182114, Mar-20; 182119, 182120, Jun-20

Class II Drugs Event

Event ID:
82335

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Preferred Pharmaceuticals, Inc
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
California, Georgia, Indiana

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 50 mg, a) 30-count bottle (NDC: 68788-6882-03), b) 90-count bottle (NDC: 68788-6882-09), Rx Only, Mfg: Torrent Pharma Inc. Basking Ridge, NJ. Relabeled by: Preferred Pharmaceuticals, Inc. 1250 N. Lakeview Ave., Suite O, Anaheim, CA 92807.

Product Quantity:
530

Reason for Recall:
CGMP Deviations: presence of an impurity, N-Methylnitrosobutyric acid (NMBA) was identified.

Recall Number:
D-1051-2019

Code Information:
Count, lots, expiry: a) 30-count bottle C2218C, exp 9/2020, D1318E, exp 10/2020; b) 90-count bottle C2719J, exp 9/2020, E1818B, exp 10/2020.

Class II Drugs Event

Event ID:
82337

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/07/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharmaceuticals, Inc.
250 Pehle Ave Ste 601
Saddle Brook NJ United States

Distribution Pattern:
Product was distributed to 6 major distributors who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Valsartan Tablets 40 mg USP, 30 tablet bottles, Rx, Only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ, Manufactured by: Aurolife Pharma LLC, Dayton, NJ ---- NDC 52343-122-30

Product Quantity:
30,530 bottles

Reason for Recall:
CGMP Deviations; Detection of a trace amount of unexpected impurity N- nitrosodiethylamine (NDEA) found in finished products

Recall Number:
D-1052-2019

Code Information:
470170038A, exp. date 10/31/2019 470180010A, exp. date 02/29/2019 470180012A, exp. date 03/31/2020

Product Description:
Valsartan Tablets 80 mg USP, 90 tablet bottles, Rx only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 --- NDC 52343-123-90

Product Quantity:
37,410 bottles

Reason for Recall:
CGMP Deviations; Detection of a trace amount of unexpected impurity N- nitrosodiethylamine (NDEA) found in finished products

Recall Number:
D-1053-2019

Code Information:
471170019A, exp. date 10/31/2019 471180006A, exp. date 03/31/2020 471180007A, exp. date 03/31/2020 471180016A, exp. date 05/31/2020

Product Description:
Valsartan Tablets 160 mg USP, 90 tablet bottles, Rx only, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 ---- NDC 52343-124-90

Product Quantity:
35,281 bottles

Reason for Recall:
CGMP Deviations; Detection of a trace amount of unexpected impurity N- nitrosodiethylamine (NDEA) found in finished products

Recall Number:
D-1054-2019

Code Information:
472180005B, exp. date 02/29/2020 472180011A, exp. date 04/30/2020 472180012A, exp. date 04/30/2020

Product Description:
Valsartan Tablets 320 mg USP, 90 tablet bottles, Distributed by: Acetris Health, LLC, Saddle Brook, NJ 07663, Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810 --- NDC 52343-125-90

Product Quantity:
42,016 bottles

Reason for Recall:
CGMP Deviations; Detection of a trace amount of unexpected impurity N- nitrosodiethylamine (NDEA) found in finished products

Recall Number:
D-1055-2019

Code Information:
473180007A, exp. date 03/31/2020 473180008A, exp. date 03/31/2020 473180011A, exp. date 04/30/2020 473180020B1, exp. date 07/31/2020 473170019B, exp. date 10/31/2019

Class II Drugs Event

Event ID:
82375

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/12/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/20/2019

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 and Puerto Rico

Associated Products

Product Description:
Hydrocortisone and Acetic Acid Otic Solution, USP, 10 mL per dropper bottle, Rx only, Hi-Tech Pharmacal Co, Inc., Amityville, NY 11701. NDC: 50383-901-10

Product Quantity:
15,322 10 ml bottles

Reason for Recall:
Sub Potent Drug: OOS results observed for the Hydrocortisone assay during routine stability testing at 12 month controlled room temperature.

Recall Number:
D-1011-2019

Code Information:
Lot: 357647, EXP 04/2019

Class II Drugs Event

Event ID:
82397

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/18/2019

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

Recalling Firm:
Iso-Tex Diagnostics, Inc
1511 County Road 129
Alvin TX United States

Distribution Pattern:
TN

Associated Products

Product Description:
Volumex (Iodinated I 131 Albumin) Injection USP, 25 uCi per 1 mL syringe, Rx Only, Manufactured for Daxor Corp., NY, NY; By: Iso-Tex Diagnostics, Inc.; NDC 50914-7720-8.

Product Quantity:
54 syringes

Reason for Recall:
Lack of Assurance of Sterility: preliminary environmental monitoring report exceeds limits, therefore sterility cannot be assured.

Recall Number:
D-1008-2019

Code Information:
Lot: V190603-922, Exp. 04/05/19

Class II Drugs Event

Event ID:
82398

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/21/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
HYDROmorphone HCl 1 mg in 0.9% Sodium Chloride, QS 5 mL Injectable Solution 1 mg/5 mL (0.2 mg per mL), Sterile single use syringe, NDC: 42852-289-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
2400 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1016-2019

Code Information:
Lots: 12/03/18 4090 28967S Exp. 4/2/2019; 12/03/18 6221 28967S Exp. 4/2/2019

Product Description:
fentaNYL 1000 mcg/100 mL Injectable Solution Fentanyl 0.9% Sodium Chloride, QS, 100 mL, Sterile single use bag, NDC: 42852-210-10 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
360 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1017-2019

Code Information:
Lot: 01/03/19 1311 21010P Exp. 5/3/2019

Product Description:
fentaNYL 2500 mcg/250 mL Injectable Solution, Fentanyl 0.9% Sodium Chloride, QS, Sterile single use bags, NDC: 42852-210-25 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
180 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1018-2019

Code Information:
Lot: 01/03/19 1645 21025P Exp. 5/3/2019

Product Description:
Midazolam Benzodiazepine 50 mg/50 mL (1 mg/mL) Injectable Solution, Midazolam HCl 0.9% Sodium Chloride, QS, Sterile single use bag, NDC: 42852-401-05 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1125 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1019-2019

Code Information:
Lots: 12/03/18 9479 40105P Exp. 4/2/2019; 12/3/18 6583 40105P Exp. 4/2/2019; 12/3/18 8918 40105P Exp. 4/2/2019; 12/03/18 4727 40105P Exp. 4/2/2019

Product Description:
Phenylephrine HCl, 500 mcg in 0.9% Sodium Chloride, QS 5 mL Injectable Solution 500 mcg/5 mL (100 mcg per mL), 5mL Sterile single use syringe, NDC: 42852-830-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
16075 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1020-2019

Code Information:
Lots: 01/18/19 3261 83067S Exp. 6/17/2019; 10/18/18 0212 83067S Exp. 3/17/2019; 10/23/18 7704 83067S Exp. 3/22/2019; 11/02/18 5909 83067S Exp. 4/1/2019; 10/31/18 8995 83067S Exp. 3/30/2019; 10/22/18 2570 83067S Exp. 3/21/2019; 10/18/18 6471 83067S Exp. 3/17/2019; 11/05/18 5527 83067S Exp. 4/4/2019; 11/05/18 0985 83067S Exp. 4/4/2019; 10/22/18 9234 83067S Exp. 3/21/2019; 10/30/18 6678 83067S Exp. 3/29/2019

Product Description:
Glycopyrrolate Injectable Solution 1 mg/5 mL (0.2 mg per mL), Sterile single use syringe, NDC: 42852-828-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
2580 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1021-2019

Code Information:
Lot: 12/05/18 0710 82867S Exp. 5/4/2019; 10/24/18 0014 82867S Exp. 3/23/2019; 11/01/18 8800 82867S Exp. 3/31/2019

Product Description:
Phenylephrine HCl, 400 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 400 mcg/10 mL (40 mcg per mL), Sterile single use syringe, NDC: 42852-876-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1575 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1022-2019

Code Information:
Lots: 10/18/18 1430 87661S Exp. 3/17/2019; 10/29/18 1805 87661S Exp. 3/28/2019

Product Description:
Phenylephrine HCl, 1 mg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 1 mg/10 mL (100 mcg per mL), Sterile single use syringe, NDC: 42852-830-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
22900 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1023-2019

Code Information:
Lots: 10/24/18 3318 83061S Exp. 3/23/2019; 10/18/18 3354 83061S Exp. 3/17/2019; 10/23/2018 6050 83061S Exp. 3/22/2019; 10/23/18 8105 83061S Exp. 3/22/2019; 10/18/18 1961 83061S Exp. 3/17/2019; 10/18/18 2598 83061S Exp. 3/17/2019; 11/05/18 1184 83061S Exp. 4/4/2019; 10/22/18 0737 83061S Exp. 3/21/2019; 10/25/18 1198 83061S Exp. 3/24/2019; 11/06/18 4451 83061S Exp. 4/5/2019; 11/06/18 0108 83061S Exp. 4/5/2019; 10/22/18 1530 83061S Exp. 3/21/2019

Product Description:
Neostigmine Methylsulfate Injection Solution 5 mg/5mL (1 mg per mL), 5mL Sterile single use syringe, For IV use only, NDC: 42852-829-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
5700 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1024-2019

Code Information:
Lots: 11/02/18 9350 82967S Exp. 4/1/2019; 10/23/18 1471 82967S Exp. 3/22/2019; 10/24/18 4412 82967S Exp. 3/23/2019; 10/24/18 0733 82967S Exp. 3/22/2019

Product Description:
Glycopyrrolate 0.6 mg/3 mL (0.2 mg per mL) Injectable Solution, 3 mL Sterile single use syringe, For IV or IM use, NDC: 42852-828-22 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
140 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1025-2019

Code Information:
Lots: 10/31/18 2288 82822S Exp. 3/30/2019; 10/18/18 8371 82822S Exp. 3/17/2019

Product Description:
2% Lidocaine HCl Injectable Solution, 60 mg/3 mL (20 mg per mL), 3mL Sterile single use syringe, NDC: 42852-011-22 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1540 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1026-2019

Code Information:
Lot: 10/18/18 2217 01122S Exp. 3/17/2019

Product Description:
2% Lidocaine HCl Injectable Solution, 100 mg/5 mL (20 mg per mL), 5mL Sterile single use syringe, NDC: 42852-011-67 Avella of Houston 9265

Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1980 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1027-2019

Code Information:
Lot: 10/19/18 1990 01167S Exp. 3/18/2019

Product Description:
Phenylephrine HCl, 800 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution, 800 mcg/10 mL (80 mcg per mL), 10mL Sterile single use syringe, NDC: 42852-865-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
800 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1028-2019

Code Information:
Lots: 10/17/18 2976 86561S Exp. 3/16/2019

Product Description:
Esmolol HCl Injectable Solution 100 mg/10 mL (10 mg per mL)10mL Sterile single use syringe, NDC: 42852-827-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
550 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1029-2019

Code Information:
Lot: 11/06/18 5007 82761S Exp. 4/5/2019

Product Description:
Heparin 10 Units/10 mL 10 Units in 0.45% Sodium Chloride, QS 10 mL, Injectable Solution, Dwell, 10mL Sterile single use syringe, NDC: 42852-725-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
500 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1030-2019

Code Information:
Lot: 10/23/18 1998 72561SPF Exp. 3/22/2019

Product Description:
Heparin 5,000 Units/5mL (1,000 Units per mL) Injectable Solution, 5,000 Units in 0.9% Sodium Chloride, QS 5 mL Sterile single use syringe, NDC: 42852-739-67 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1440 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1031-2019

Code Information:
Lot: 10/25/18 4819 73967S Exp. 3/24/2019

Product Description:
Phenylephrine HCl, 1 mg in Sterile Water for Injection, QS 10 mL Injectable Solution 1 mg/10 mL (100 mcg per mL) NDC: 42852-802-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
1850 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1032-2019

Code Information:
Lot: 11/01/18 8847 80261S Exp. 3/31/2019

Product Description:
Morphine Sulfate 30 mg/30 mL (1 mg/mL) Injectable Solution Morphine Sulfate 30 mg 0.9% Sodium Chloride QS 30 mL Sterile singe use syringe, NDC: 42852-241-63 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
2325 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1033-2019

Code Information:
Lots: 10/19/18 2117 24163M Exp. 3/18/2019; 11/5/18 1363 24163M Exp. 4/4/2019; 11/5/18 1511 24163M Exp. 4/4/2019; 10/19/18 2061 24163M Exp. 3/18/2019; 10/23/18 1963 14163M Exp. 3/22/2019; 10/19/18 1441 24163M Exp. 3/18/2019

Product Description:
Phenylephrine HCl, 1,200 mcg in 0.9% Sodium Chloride, QS 10 mL Injectable Solution 1,200 mcg/10 mL (120 mcg per mL), Sterile single use syringe, NDC: 42852-882-61 Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404

Product Quantity:
975

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-1034-2019

Code Information:
Lot: 11/05/18 7020 88261S, exp 4/4/2019

Class III Drugs Event

Event ID:
82367

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA

1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide in the United States.

Associated Products

Product Description:
Lansoprazole Delayed-Release Orally Disintegrating Tablets, 15 mg, 100 tablets (10 blister cards of 10 tablets each), Rx only, Manufactured in Israel By: Teva Pharmaceutical Ind. Ltd. Jerusalem, 9777402, Israel, Manufactured for: Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0093-3008-93

Product Quantity:
7,081 bottles

Reason for Recall:
Subpotent Drug.

Recall Number:
D-1006-2019

Code Information:
Lot #: 25Q002, Exp. 11/2019

Class III Drugs Event

Event ID:
82392

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/19/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Recalled product was distributed to 7 major wholesale/drug chain distributors and 1 supermarket chain that may have further distribute the product throughout the United States.

Associated Products

Product Description:
Testosterone Topical Solution, 30mg/1.5mL, 110mL bottles, Rx only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775 INDIA, NDC 68180-943-11

Product Quantity:
3,200 bottles

Reason for Recall:
Defective Container: Repetitive complaints received indicating pump not working.

Recall Number:
D-1010-2019

Code Information:
Lot # K700086, Exp 11/2019

Not Yet Classified Drugs Event

Event ID:
82198

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Heritage Pharmaceuticals, Inc.
1 Tower Center Blvd Ste 1700
East Brunswick NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Etomidate Injection, USP 20 mg/10mL (2mg/mL) 10 mL Single-Dose Vial, Rx only, Manufactured for: Heritage Pharmaceuticals Inc. Made in India, NDC 23155-160-31

Product Quantity:
11888 units

Reason for Recall:
Subpotent Drug.

Recall Number:

Code Information:
Lot #: AMA701, Exp. March 2019; AMA702, AMA703, Exp August 2019.