

Enforcement Report - Week of November 7, 2018

Class II Drugs Event

Event ID:

81002

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

09/10/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

11/01/2018

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Pharm D Solutions, LLC
1304 S Loop W
Houston TX United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

Acetylcysteine Injection 10 mg/5 mL (2 mg/mL), Pharm D Solutions, Houston, Texas ---- NDC 69699-1424-10

Product Quantity:

486 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0136-2019

Code Information:

Lots: 07032018:93 Discard by: 01/03/2019; 07032018:27 Discard by: 01/03/2019; 07032018:97 Discard by: 01/03/2019

Product Description:

Arginine Injections 100 mcg/mL, Pharm D Solutions, Houston, Texas NDC 69699-1414-20

Product Quantity:

7150 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0137-2019

Code Information:

Lots: 04112018:83 Discard by: 10/8/2018; 03202018:48 Discard by: 9/16/2018; 04302018:91 Discard by: 10/27/2018

Product Description:

Ascorbic Acid 500 mg/mL Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1502-50

Product Quantity:

10000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0138-2019

Code Information:

Lot: 04252018:91 Discard by: 10/21/2018

Product Description:

Beta-complex B-1, B-6, B-3, B-12, B-5 100, 2.54 Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1611-30

Product Quantity:

6000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0139-2019

Code Information:

Lot: 06182018:55 Discard by: 12/25/2018

Product Description:

Bacteriostatic Water for Injection 10 mL, Pharm D Solutions, Houston, Texas --- NDC 69699-1417-10

Product Quantity:

285 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0140-2019

Code Information:

Lots: 07182018:12 Discard by: 1/14/2019; 04042018:68 Discard by: 9/30/2018; 05152018:57 Discard by: 11/10/2018; 06202018:17 Discard by: 12/17/2018

Product Description:

Bi-Mix Injection (Alprostadil 150 mcg/Lidocaine 2 mg/mL), Pharm D Solutions, Houston, Texas --- NDC 69699-1323-05

Product Quantity:

130 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0141-2019

Code Information:

Lots: 04112018:34 Discard by: 10/7/2018; 08012018:66 Discard by: 1/28/2019; 07262018:34 Discard by: 1/8/2019

Product Description:

Bi-Mix Injection, (Alprostadil 40 mcg/Lidocaine 2 mg/mL) Pharm D Solutions, Houston, Texas --- NDC 69699-1305-03

Product Quantity:

148 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0142-2019

Code Information:

Lots: 04112018:37 Discard by: 10/1/2018; 06202018:70 Discard by: 12/16/2018; 08082018:95 Discard by: 2/4/2019

Product Description:

Bi-Mix Injection (Alprostadil 80 mcg/Lidocaine 2 mg/mL) Pharm D Solutions, Houston, Texas --- NDC 69699-1317-03

Product Quantity:

115 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0143-2019

Code Information:

Lots: 04112018:50 Discard by: 10/7/2018; 08082018:53 Discard by: 2/4/2019

Product Description:

Bi-Mix (Papaverine/Phentolamine 150 mg/5 mg) a) Injectable NDC 69699-1760-15; b) (LYO) Powder NDC 69699-1760-15, Pharm D Solutions, Houston, Texas

Product Quantity:

29 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0144-2019

Code Information:

Lots: a)04032018:49 Discard by: 9/30/2018; 05242018:72 Discard by: 11/20/2018; b) 06192018:08 Discard by: 12/16/2018; 06132018:29 Discard by: 12/10/2018

Product Description:

Caffeine and Sodium Benzoate Injection 125 mg/125 mg/mL Injectable Pharm D Solutions, Houston, Texas ---- NDC 69699-1428-02

Product Quantity:

567 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0145-2019

Code Information:

Lots: 07192018:88 Discard by: 10/16/2018

Product Description:

Calcium Gluconate 1% Eyewash Oph. Soln, 10 mg/mL, 1000 mL bottles, Pharm D Solutions, Houston, Texas ---- NDC 69699-0907-10

Product Quantity:

25 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0146-2019

Code Information:

Lots: 05072018:27 Discard by: 5/2/2019; 07122018:11 Discard by 7/7/2019

Product Description:

Calcium Gluconate 1% Eyewash 10 mg/mL, 125 mL bottles, Pharm D Solutions, Houston, Texas ---- NDC 69699-0906-12

Product Quantity:

29 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0147-2019

Code Information:

Lots: 05072018:46 Discard by: 5/1/2019; 07122018:30 Discard by: 7/7/2019

Product Description:

Calcium Gluconate 10%, 100 mg/mL Injectable, Pharm D Solutions, Houston, Texas ---- NDC 69699-0914-30

Product Quantity:

6850 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0148-2019

Code Information:

Lots: 07312018:46 Discard by: 1/27/2019; 07262018:97 Discard by: 1/21/2019; 07122018:40 Discard by: 1/8/2019

Product Description:

Dexpanthenol Injection, 250 mg/mL Pharm D Solutions, Houston, Texas --- NDC 69699-1610-30

Product Quantity:

2000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0150-2019

Code Information:

Lot: 08292018:08 Discard by: 2/23/2019

Product Description:

Epi-Shugarcaine Kit Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1409-60

Product Quantity:

70 bottles

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0151-2019

Code Information:

08272018:79 Discard by: 10/1/2018

Product Description:

Epinepherine 1 mg/1 mL 3 mL Injectable Pharm D Solutions, Houston, Texas ---- NDC 69699-0109-03

Product Quantity:

945 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0152-2019

Code Information:

Lots: 07272018:17 Discard by: 9/25/2018; 08292018:74 Discard by: 10/28/2018

Product Description:

Glutamine 10 mg/mL Solution, Pharm D Solutions, Houston, Texas ---- NDC 69699-1439-59

Product Quantity:

1095 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0153-2019

Code Information:

Lots: 01402018:93 Discard by: 10/10/2018; 07122018:16 Discard by: 9/10/2018; 08302018:65 Discard by:

Product Description:

Glutathione 200 mg/mL Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1504-30

Product Quantity:

4000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0154-2019

Code Information:

Lot: 08012018:94 Discard by: 1/27/2019

Product Description:

Glycerin 72% (Lidocaine/Epi 2:1) Injectable, Pharm D Solutions, Houston, Texas ---- NDC 69699-1401-30

Product Quantity:

180 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0155-2019

Code Information:

Lot: 07312018:13 Discard by: 9/28/2018

Product Description:

HCG Lyophilized 5000 IU Injectable Pharm D Solutions, Houston, Texas ---- NDC 69699-1707-10

Product Quantity:

2219 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0156-2019

Code Information:

Lot: 04252018:33 Discard by: 10/21/2018; 05082018:39 Discard by: 11/4/2018; 06262018:00 Discard by: 12/23/2018; 07192018:13 Discard by: 1/15/2019; 08012018:46 Discard by: 1/28/2019; 08212018:69 Discard by: 11/30/2018

Product Description:

HCG Reconstituted 50,000 IU Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1736-50

Product Quantity:

3 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0157-2019

Code Information:

Lot: 09062018:07 Discard by: 10/6/2018

Product Description:

HCG Reconstituted 6000 IU Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1739-06

Product Quantity:

10 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0158-2019

Code Information:

Lot: 09062018:83 Discard by: 10/6/2018

Product Description:

HCG 10,000 unit/0.3 gm Mannitol Lyophilized, Pharm D Solutions, Houston, Texas ---- NDC 69699-1711-10

Product Quantity:

1171 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0159-2019

Code Information:

Lot: 04182018:46 Discard by: 10/14/2018; 06072018:65 Discard by: 12/3/2018; 05082018:01 Discard by: 11/4/2018; 07282018:20 Discard by: 1/24/2019

Product Description:

HCG Lyophilized 1200 IU Injectable, Pharm D Solutions, Houston, Texas ---- NDC 69699-1743-12

Product Quantity:

881 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0160-2019

Code Information:

Lot: 04092018:58 Discard by: 10/6/2018; 06072018:03 Discard by: 12/4/2018; 05292018:86 Discard by: 11/25/2018; 07192018:64 Discard by: 1/15/2019; 08302018:30 Discard by: 2/26/2019

Product Description:

HCG 3000 Unit Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1738-10

Product Quantity:

765 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0161-2019

Code Information:

Lot: 03262018:79 Discard by: 9/22/2018; 08212018:75 Discard by: 2/17/2019

Product Description:

HCG 4000 Unit Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1704-01

Product Quantity:

2737 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0162-2019

Code Information:

Lot: 03142018:73 Discard by: 3/9/2019; 04122018:64 Discard by: 4/7/2019; 07162018:84 Discard by: 7/11/2019; 06192018:36 Discard by: 6/12/2019; 08062018:28 Discard by: 8/1/2019

Product Description:

HCG 50,000 unit/0.3 gm Mannitol Lyophilized Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1736-50

Product Quantity:

114 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0163-2019

Code Information:

Lot: 04092018:36 Discard by: 10/6/2018; 05292018:93 Discard by: 11/25/2018; 08062018:96 Discard by: 2/2/2019; 07022018:64 Discard by: 7/6/2018

Product Description:

HCG 6000 unit/0.3 gm Mannitol Lyophilized 6000 IU/vial injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1739-06

Product Quantity:

442 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0164-2019

Code Information:

Lot: 04092018:14 Discard by: 10/6/2018; 06042018:54 Discard by: 12/1/2018; 05292018:81 Discard by: 11/25/2018

Product Description:

Levocarnitine 170 mg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1617-10

Product Quantity:

3000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0165-2019

Code Information:

Lot: 04232018:63 Discard by: 10/20/2018

Product Description:

Lipo MIC-12 Compound Injectable a) NDC 69699-1603-10; b) 30 mL Stock Solution Compound Injectable NDC 69699-1603-30, Pharm D Solutions, Houston, Texas

Product Quantity:

896 vials; 64000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0166-2019

Code Information:

Lot: a) 09042018:66/A Discard by: 3/3/2019; 07302018:65 Discard by: 1/26/2019; b) 08132018:75/A Discard by: 2/1/2019; 04172018:16 Discard by: 9/30/2018; 03212018:27 Discard by: 9/17/2018; 04242018:82 Discard by: 10/20/2018; 05142018:72 Discard by: 11/10/2018; 06192018:67 Discard by: 12/18/2018; 08142018:00 Discard by: 2/1/2019; 07302018:64 Discard by: 1/26/2019

Product Description:

Magnesium 40 gm/ns 1000 mL IV, Pharm D Solutions, Houston, Texas --- NDC 69699-0904-10

Product Quantity:

4 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0167-2019

Code Information:

Lot: 05242018:04 Discard by: 8/22/2018

Product Description:

Methylcobalamin 1 mg/mL a) 10 mL Injectable NDC 69699-1501-10; b) 30 mL Injectable NDC 69699-1501-30, Pharm D Solutions, Houston, Texas

Product Quantity:

24500 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0168-2019

Code Information:

Lot: a) 04242018:27 Discard by: 9/15/2018; 04302018:55 Discard by: 10/27/2018; b) 03192018:33 Discard by: 9/15/2018; 05222018:28 Discard by: 11/18/2018

Product Description:

Oxytocin 30 unit in LR 500 mL 0.06 units/mL IV, Pharm D Solutions, Houston, Texas --- NDC 69699-1203-50

Product Quantity:

264 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0169-2019

Code Information:

Lot: 03152018:12 Discard by: 6/13/2018; 04182018:08 Discard by: 7/17/2018; 04302018:94 Discard by: 7/29/2018; 03292018:44 Discard by: 6/26/2018; 05212018:95 Discard by: 8/19/2018; 06142018:46 Discard by: 9/12/2018; 05312018:37 Discard by: 8/29/2018; 06282018:80 Discard by: 9/26/2018; 07312018:12 Discard by: 10/29/2018; 07102018:53 Discard by: 10/8/2018; 08222018:18 Discard by: 11/20/2018

Product Description:

Phenol 5% and Glycerin Aqueous Solution 10 mL Injection, Pharm D Solutions, Houston, Texas --- NDC 69699-1431-10

Product Quantity:

1139 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0170-2019

Code Information:

Lot: 05082018:59 Discard by: 11/4/2018; 08082018:57 Discard by: 2/4/2019

Product Description:

Phenol 7% and Glycerin Aqueous Solution 10 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1432-10

Product Quantity:

630 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0171-2019

Code Information:

Lot: 08082018:86 Discard by: 2/4/2019

Product Description:

Phosphate Buffer Solution 0.05 m Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-0912-20

Product Quantity:

1900 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0172-2019

Code Information:

Lot: 06252018:63 Discard by: 12/22/2018; 07312018:35 Discard by: 1/26/2019

Product Description:

Prostaglandin E1 150 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1623-05

Product Quantity:

193 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0173-2019

Code Information:

Lot: 04262018:18 Discard by: 10/22/2018; 03292018:66 Discard by: 9/24/2018; 05312018:19 Discard by: 11/27/2018; 07022018:55 Discard by: 12/29/2018; 06122018:51 Discard by: 12/9/2018; 07242018:71 Discard by: 1/20/2019; 08302018:90 Discard by: 2/23/2019

Product Description:

Prostaglandin E1 40 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1347-05

Product Quantity:

154 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0174-2019

Code Information:

Lot: 04262018:95 Discard by: 10/22/2018; 03292018:59 Discard by: 9/24/2018; 05312018:66 Discard by: 11/27/2018; 06122018:07 Discard by: 12/9/2018

Product Description:

Prostaglandin E1 80 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1337-05

Product Quantity:

189 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0175-2019

Code Information:

Lot: 04252018:84 Discard by: 10/22/2018; 03292018:62 Discard by: 9/24/2018; 05312018:52 Discard by: 11/27/2018; 07022018:82 Discard by: 11/17/2018; 06122018:96 Discard by: 12/9/2018; 07242018:22 Discard by: 1/20/2019; 08302018:71 Discard by: 2/23/2019

Product Description:

Pyridoxine 100 mg/mL, 30 mL MDV Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1614-30

Product Quantity:

600 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0176-2019

Code Information:

Lot: 03132018:47 Discard by: 9/9/2018

Product Description:

QM-4A Quadmix 5 mL 30 PA-2PH-150A-Atropine 0.4 mg Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1342-05

Product Quantity:

25 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0177-2019

Code Information:

Lot: 07242018:90 Discard by: 1/20/2019

Product Description:

Reck Injection, Pharm D Solutions, Houston, Texas --- NDC 69699-1459-50

Product Quantity:

517 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0178-2019

Code Information:

Lot: 03262018:11 Discard by: 4/25/2018; 04102018:38 Discard by: 5/10/2018; 05312018:63 Discard by: 6/30/2018; 05032018:97 Discard by: 6/2/2018; 06082018:24 Discard by: 7/8/2018; 05212018:80 Discard by: 6/20/2018; 07102018:60 Discard by: 8/9/2018; 06202018:44 Discard by: 7/19/2018; 07232018:08 Discard by: 8/22/2018; 07022018:62 Discard by: 8/1/2018; 08292018:95 Discard by: 9/28/2018; 08202018:61 Discard by: 9/19/2018

Product Description:

Sermorelin/Ipamorelin 18 mg/15 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1759-18

Product Quantity:

179 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0179-2019

Code Information:

Lot: 07272018:31 Discard by: 1/23/2019

Product Description:

Sermorelin/GHRP-2 6 mg/6 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1727-10

Product Quantity:

409 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0180-2019

Code Information:

Lot: 05012018:48 Discard by: 10/28/2018; 05242018:32 Discard by: 11/20/2018; 06112018:53 Discard by: 12/8/2018

Product Description:

Sermorelin/GHRP-2 18 mg/6 mg powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1748-10

Product Quantity:

124 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0181-2019

Code Information:

Lot: 04232018:89 Discard by: 10/15/2018

Product Description:

Sermorelin/GHRP-2 9 mg-6 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1728-10

Product Quantity:

330 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0182-2019

Code Information:

Lot: 03202018:06 Discard by: 9/16/2018; 06112018:49 Discard by: 12/8/2018

Product Description:

Sermorelin/GHRP-2 9 mg/9 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1715-10

Product Quantity:

250 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0183-2019

Code Information:

Lot: 03202018:46 Discard by: 9/16/2018; 05012018:56 Discard by: 10/28/2018

Product Description:

Sermorelin/GHRP-2/GHRP-6 Mannitol 9 mg/9 mg/9 mg/300 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1726-10

Product Quantity:

420 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0184-2019

Code Information:

Lot: 04232018:46 Discard by: 10/13/2018; 06252018:30 Discard by: 12/22/2018; 07232018:10 Discard by: 1/19/2019; 08302018:07 Discard by: 2/25/2019

Product Description:

Sermorelin/GHRP-2/Theanine/Mannitol 15 mg/6 mg/75 mg/300 mg Powder, Pharm D Solutions, Houston, Texas --- NDC 69699-1731-10

Product Quantity:

108 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0185-2019

Code Information:

Lot: 07062018:05 Discard by: 1/2/2019

Product Description:

Slenderella Compound Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1617-30

Product Quantity:

5000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0186-2019

Code Information:

Lot: 04202018:59 Discard by: 10/17/2018; 08282018:46 Discard by: 2/1/2019

Product Description:

0.9% Sodium Chloride for Injection, 50 mL bags, Pharm D Solutions, Houston, Texas --- NDC 69699-1426-10

Product Quantity:

12 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0187-2019

Code Information:

Lot: 04192018:13 Discard by: 10/16/2018

Product Description:

Sterile Water 50 mL Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1421-50

Product Quantity:

10 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0188-2019

Code Information:

Lot: 08092018:38 Discard by: 2/5/2018

Product Description:

Tilarginine Acetate 50 mg/mL, 10 mL, Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1461-10

Product Quantity:

3523 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0189-2019

Code Information:

Lot: 06212018:28 Discard by: 12/11/2019; 06152018:24 Discard by: 12/12/2018

Product Description:

Tri-Mix XL 150 mg/10 mg/100 mcg a) Injectable NDC 69699-1353-10; b) (LYO) Powder NDC 69699-1353-10, Pharm D Solutions, Houston, Texas

Product Quantity:

553 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0190-2019

Code Information:

Lot: a) 04132018:97 Discard by: 10/10/2018; 04032018:25 Discard by: 9/30/2018; b) 04162018:29 Discard by: 10/11/2018; 03282018:80 Discard by: 9/24/2018; 06122018:06 Discard by: 12/9/2018; 08132018:55 Discard by: 2/9/2019

Product Description:

Tri-Mix Papaverine/Phentolamine/Alprostadil 150 mg/5 mg/50 mcg a) Injectable NDC 69699-1332-05 b) (LYO) Powder NDC 69699-1332-05, Pharm D Solutions, Houston, Texas

Product Quantity:

609 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0191-2019

Code Information:

Lot: a) 09062018:87 Discard by: 1/14/2019 b) 04042018:44 Discard by: 10/29/2018; 09022018:04 Discard by: 3/1/2019; 05212018:44 Discard by: 11/17/2018; 06122018:83 Discard by: 12/9/2018; 08132018:86 Discard by: 2/9/2019

Product Description:

Trimix BM3 Papaverine 60 mg/Phentolamine 4 mg Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1310-03

Product Quantity:

67 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0192-2019

Code Information:

Lot: 05072018:35 Discard by: 11/3/2018; 06122018:01 Discard by: 12/9/2018

Product Description:

Trimix BM3 Papaverine 30 mg/Phentolamine 1 mg Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1354-03

Product Quantity:

20 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0193-2019

Code Information:

Lot: 07262018:58 Discard by: 1/21/2019

Product Description:

Trimix QM10 Papaverine 30 mg/Phentolamine 4 mg/Atropine 1 mg/PGE 150 mcg/mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1352-05

Product Quantity:

9 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0194-2019

Code Information:

Lot: 04262018:09 Discard by: 10/22/2018; 07022018:48 Discard by: 12/29/2018

Product Description:

Trimix T 101 Alprostadil/Papverine/Phentolamine 5.9 mcg/17.65 mg/0.59 mcg per mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1336-05

Product Quantity:

20 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0195-2019

Code Information:

Lot: 05312018:22 Discard by: 6/30/2018

Product Description:

Trimix 30-1-30 Papavarin 30 mg/Phentolamine 1 mg/Alprostadil 30 mg/mL Aqueous Solution, Pharm D Solutions, Houston, Texas --- NDC 69699-1319-10

Product Quantity:

50 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0196-2019

Code Information:

Lot: 06192018:98 Discard by: 12/16/2018

Product Description:

Trimix Alprostadil/ Phentolamine/Papavarin 40 mcg/1 mg/30 mg 10 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1330-05

Product Quantity:

65 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0197-2019

Code Information:

Lot: 08062018:52 Discard by: 10/5/2018; 08012018:08 Discard by: 9/30/2018

Product Description:

Trimix AT-6 Papa 30 mg/Phent 4 mg/Atrop. 0.3 mg Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1343-05

Product Quantity:

40 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0198-2019

Code Information:

Lot: 04262018:90 Discard by: 10/22/2018; 05312018:92 Discard by: 11/27/2018

Product Description:

Trimix Papaverine/Phentolamine/Alprostadil 30 mg/1 mg/10 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1365-10

Product Quantity:

715 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0199-2019

Code Information:

Lot: 03292018:02 Discard by: 9/24/2018; 05302018:54 Discard by: 11/26/2018; 06062018:79 Discard by: 12/3/2018; 06122018:31 Discard by: 11/17/2018; 07252018:44 Discard by: 1/21/2019

Product Description:

Trimix Papaverine/Phentolamine/Alprostadil 30 mg/1 mg/20 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1366-02

Product Quantity:

815 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0200-2019

Code Information:

Lot: 03292018:70 Discard by: 9/25/2018; 05302018:94 Discard by: 11/26/2018; 06072018:67 Discard by: 12/4/2018; 06122018:72 Discard by: 12/9/2018; 07252018:72 Discard by: 1/21/2019

Product Description:

Trimix Papaverine/Phentolamine/Alprostadil 30 mg/1 mg/60 mcg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1367-02

Product Quantity:

430 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0201-2019

Code Information:

Lot: 06132018:87 Discard by: 12/10/2018; 05302018:66 Discard by: 11/25/2018; 06122018:54 Discard by: 11/17/2018; 07252018:88 Discard by: 1/21/2019

Product Description:

Trimix Papaverine/Phentolamine/Alprostadil/Lidocaine 30 mg/1 mg/175 mcg/1 mg Powder Pharm D Solutions, Houston, Texas --- NDC 69699-1369-02

Product Quantity:

195 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0202-2019

Code Information:

Lot: 05302018:59 Discard by: 11/26/2018; 06132018:44 Discard by: 12/10/2018; 06062018:64 Discard by: 12/3/2018; 07262018:97 Discard by: 11/1/2018; 07052018:23 Discard by: 1/1/2019

Product Description:

Trimix ST-1 30PA-1.5PH-50A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1388-05

Product Quantity:

40 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0203-2019

Code Information:

Lot: 05312018:12 Discard by: 11/27/2018; 07242018:04 Discard by: 1/20/2019

Product Description:

Trimix ST-9B 30 PA-2PH-100A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1344-05

Product Quantity:

59 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0204-2019

Code Information:

Lot: 04262018:54 Discard by: 10/23/2018; 03292018:91 Discard by: 9/24/2018; 05312018:10 Discard by: 11/27/2018

Product Description:

Phentolamine 1 mg/Papaverine 15 mg/Alprostadil 150 mcg Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1308-03

Product Quantity:

343 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0205-2019

Code Information:

Lot: 04102018:07 Discard by: 10/7/2018; 05102018:18 Discard by: 11/6/2018; 05222018:64 Discard by: 8/1/2018; 07022018:46 Discard by: 12/29/2018; 08012018:81 Discard by: 1/28/2019; 06202018:97 Discard by: 9/17/2018

Product Description:

Trimix ST9D 30PA-2PH-150A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1311-03

Product Quantity:

336 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0206-2019

Code Information:

Lot: 04102018:12 Discard by: 10/7/2018; 05102018:06 Discard by: 11/6/2018; 05222018:76 Discard by: 11/18/2018; 07022018:35 Discard by: 12/29/2018; 08272018:00 Discard by: 1/14/2019; 08082018:14 Discard by: 2/4/2019

Product Description:

Trimix T-101 Alprostadil/Phapaverine/Phentolamine 5.9 mcg/17.65 mg/Phentolamine 0.59 mcg per mL Pharm D Solutions, Houston, Texas --- NDC 69699-1366-05

Product Quantity:

10 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0207-2019

Code Information:

Lot: 07242018:35 Discard by: 8/23/2018

Product Description:

Trimix T-106 30PA-1PH-25A Aqueous Solution Pharm D Solutions, Houston, Texas --- NDC 69699-1339-05

Product Quantity:

44 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0208-2019

Code Information:

Lot: 03292018:66 Discard by: 9/24/2018; 05312018:81 Discard by: 11/27/2018

Product Description:

Trimix T105 PGE/Phentolamine/Papaverine 10 mcg/30 mg/1 mg Injectable Pharm D Solutions, Houston, Texas --- NDC 69699-1351-05

Product Quantity:

40 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0209-2019

Code Information:

Lot: 04262018:08 Discard by: 10/22/2018; 07242018:81 Discard by: 1/20/2019

Product Description:

Vigamox Oph. Solution Pharm D Solutions, Houston, Texas --- NDC 69699-0304-05

Product Quantity:

521 syringes

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0210-2019

Code Information:

Lot: 04192018:22 Discard by: 5/17/2018; 04022018:47 Discard by: 4/23/2018; 05102018:77 Discard by: 6/7/2018; 08022018:63 Discard by:

8/30/2018; 08272018:66 Discard by: 9/24/2018

Product Description:

Water Sterile for Injection 250 mL IV Pharm D Solutions, Houston, Texas --- NDC 69699-1407-25

Product Quantity:

12 bags

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0211-2019

Code Information:

Lot: 05222018:12 Discard by: 10/21/2018

Product Description:

Zinc Sulfate 1 mg/mL MDV Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1418-10

Product Quantity:

184 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0212-2019

Code Information:

Lot: 06072018:60 Discard by: 12/4/2018

Product Description:

Testosterone in Grapeseed Oil 200 mg/mL, a) 4 mL, b) 5 mL, c) 10 mL and d) 30 mL Injectable, Pharm D Solutions, Houston, Texas NDC 69699-1702-05

Product Quantity:

a) 4397, b) 4885 c) 1319, d) 4112 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0213-2019

Code Information:

Lot: a) Lot: 01302018:77/A Discard by: 1/25/2019; 09042017:74/B Discard by: 8/30/2018; 04042018:51/A Discard by: 3/31/2019; 05152018:94/A Discard by: 5/9/2019; 07022018:04/A Discard by: 6/27/2019; 07162018:80/B Discard by: 7/11/2019; 08272018:15/B Discard by: 8/22/2019; b) 12052017:13/B, Discard by: 11/30/2018; 09042017:74/A Discard by: 8/30/2018; 03212018:39/B Discard by: 3/17/2019; 01302018:77/B Discard by: 1/25/2019; 06262018:25/A Discard by: 6/21/2019; 05212018:45/A Discard by: 5/16/2019; 05152018:94/B Discard by: 5/9/2019; 07162018:80/A Discard by: 7/11/2019 c) Lot: 09132017:58/A Discard by: 9/7/2018; 03212018:39/P Discard by: 3/16/2019; 05012018:45/A Discard by: 4/26/2019; 05012018:45/P Discard by: 4/26/2019; 06042018:58/A Discard by: 5/30/2019; 05152018:94/C Discard by: 5/9/2019; 07022018:04/B Discard by: 6/27/2019 d) Lot: 01082018:40/B Discard by: 1/3/2019; 09042017:74/C Discard by: 8/30/2018; 09132017:58/B Discard by: 9/7/2018; 01302018:77/C Discard by: 1/25/2019; 03212018:39/C Discard by: 3/16/2019; 04042018:51/B Discard by: 3/30/2019; 06042018:58/B Discard by: 5/30/2019; 05012018:45/B Discard by: 4/26/2019; 06132018:02/B Discard by: 6/3/2019; 05212018:94/B Discard by: 5/9/2019; 05152018:94/D Discard by: 5/9/2019; 07162018:80/C Discard by: 7/11/2019; 08062018:67A Discard by: 8/1/2019; 07022018:04/C Discard by: 6/27/2019; 07242018:04/A Discard by: 7/19/2019; 08272018:15/A Discard by: 8/22/2019

Product Description:

Testosterone Cypionate/Propionate 200 mg/10 mg/1 mL 30 mL Injectable, Pharm D Solutions, Houston, Texas --- NDC 69699-1745-30

Product Quantity:

580 vials and 30000 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0214-2019

Code Information:

Lot: 02272018:63/A Discard by: 2/22/2019; 08162018:63/A Discard by: 4/30/2019; 10092017:30 Discard by: 10/1/2018; 02272018:63 Discard by:

2/22/2019; 08162018:63 Discard by: 4/30/2019

Class II Drugs Event

Event ID:

81218

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

10/09/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

10/30/2018

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Sprayology
18914 Bonanza Way
Gaithersburg MD United States

Distribution Pattern:

Distributed Nationwide in the USA

Associated Products

Product Description:

Rejuvenation Plus, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879 NDC 61096-0035-1

Product Quantity:

1,558 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0105-2019

Code Information:

All lots within expiry

Product Description:

Man Power, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0025-1 and Tester NDC 61096-1025-1

Product Quantity:

830 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0106-2019

Code Information:

All lots within expiry

Product Description:

Brain Power, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0033-1

Product Quantity:

2,054 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0107-2019

Code Information:

All lots within expiry

<p>Product Description: Woman Power, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879 NDC 61096-0034-1 and Tester NDC 61096-1034-1</p> <p>Product Quantity: 1,284 bottles</p> <p>Reason for Recall: CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.</p> <p>Recall Number: D-0108-2019</p> <p>Code Information: All lots within expiry</p>
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<p>Product Description: MenoPower, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0014-1 and Tester NDC 61096-1014</p> <p>Product Quantity: 2,301 bottles</p> <p>Reason for Recall: CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.</p> <p>Recall Number: D-0109-2019</p> <p>Code Information: All lots within expiry</p>

<p>Product Description: Bone Builder, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0012-1 and Tester NDC 61096-1012-1</p> <p>Product Quantity: 731 bottles</p> <p>Reason for Recall: CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.</p> <p>Recall Number: D-0110-2019</p> <p>Code Information: All lots within expiry</p>
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<p>Product Description: AllergEase, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0003-1</p> <p>Product Quantity: 4,153 bottles</p> <p>Reason for Recall: CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.</p> <p>Recall Number: D-0111-2019</p> <p>Code Information: All lots within expiry</p>
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<p>Product Description: Cold + Flu Relief, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0002-1</p> <p>Product Quantity: 2,565 bottles</p> <p>Reason for Recall: CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.</p>

Recall Number:

D-0112-2019

Code Information:

All lots within expiry

Product Description:

DigestivEase, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879.NDC 61096-0005-1

Product Quantity:

1,465 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0113-2019

Code Information:

All lots within expiry

Product Description:

SleepEase, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879.NDC 61096-0001-1 and Tester NDC 6196-1001-1

Product Quantity:

5,393 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0114-2019

Code Information:

All lots within expiry

Product Description:

TravelEase, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879NDC 61096-0007-1. and Tester NDC 61096-1007-1

Product Quantity:

1,307 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0115-2019

Code Information:

All lots within expiry

Product Description:

Party Relief, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0030-1 and Tester NDC 61096-1030-1

Product Quantity:

2,956 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0116-2019

Code Information:

All lots within expiry

Product Description:

Arnica Power, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879.NDC 61096-0032-1

Product Quantity:

3,531 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0117-2019

Code Information:

All lots within expiry

Product Description:

Snore Soother, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0024-1

Product Quantity:

1,055 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0118-2019

Code Information:

All lots within expiry

Product Description:

Stress Relief, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0006-1 and Tester NDC 61096-1006-1

Product Quantity:

3,896 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0119-2019

Code Information:

All lots within expiry

Product Description:

PMS Support, Homeopathic Oral Spray, 1.38 fl. oz (41ml), Manufactured for Sprayology Gaithersburg. MD 20879. NDC 61096-0031-1

Product Quantity:

647 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0120-2019

Code Information:

All lots within expiry

Product Description:

Life Detoxer Homeopathic Oral Spray 1.38 fl. oz. (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879 NDC 61096-0023-1 and Tester NDC 61096-1023-1

Product Quantity:

1,473 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0121-2019

Code Information:

All lots within expiry

Product Description:

ImmunoBooster, Homeopathic Oral Spray 1.38 fl. oz. (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879. NDC 61096-0038-1

Product Quantity:

2,837 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0122-2019

Code Information:

All lots within expiry

Product Description:

Body Skin Tonic, Homeopathic Oral Spray 1.38 fl. oz. (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879. NDC 61096-0017-1

Product Quantity:

857 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0123-2019

Code Information:

All lots within expiry

Product Description:

Acne Tonic Homeopathic Oral Spray 1.38 fl. oz. (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879. NDC 61096-0027-1

Product Quantity:

919 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0124-2019

Code Information:

All lots within expiry

Product Description:

Body Balance, Homeopathic Oral Spray 1.38 fl. oz (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879. NDC 61096-0039-1

Product Quantity:

2,595 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0125-2019

Code Information:

All lots within expiry

Product Description:

Diet Power, Homeopathic Oral Spray 1.38 fl. oz. (41 mL). Manufactured by Sprayology Gaithersburg, MD 20879. NDC 61096-0004-1

Product Quantity:

3634 bottles

Reason for Recall:

CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.

Recall Number:

D-0126-2019

Code Information:

All lots within expiry

Class II Drugs Event

Event ID:

81340

Status:

Ongoing

Recall Initiation Date:

10/22/2018

Center Classification Date:

11/01/2018

Recalling Firm:

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd
Ridgefield CT United States

Distribution Pattern:

Distributed nationwide in the USA and Puerto Rico

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Catapres .2 (clonidine hydrochloride, USP) 0.2mg, 100-count bottles, Rx only, Dist. by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA. Made in Germany. NDC 0597-0007-01

Product Quantity:

1,380 100-count bottles

Reason for Recall:

Failed Dissolution Specifications: OOS results during routine stability testing

Recall Number:

D-0128-2019

Code Information:

Lot: 757739, EXP 9/2020

Class II Drugs Event

Event ID:

81413

Status:

Ongoing

Recall Initiation Date:

10/19/2018

Center Classification Date:

11/01/2018

Recalling Firm:

Avella of Deer Valley, Inc. Store 38
24416 N 19th Ave
Phoenix AZ United States

Distribution Pattern:

U.S.A. nationwide.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Morphine (1 mg/mL) in NS 100 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38

Product Quantity:

1,360 bags

Reason for Recall:

Lack of assurance of sterility

Recall Number:

D-0131-2019

Code Information:

Lot # 7/10/18 0415 24110P, Exp 11/07/2018; 7/25/18 0247 24110P, Exp 11/22/2018

Product Description:

Fentanyl (10 mcg/mL) in NS 1 mL (in 3mL BD Syringe), Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38

Product Quantity:

20 syringes

Reason for Recall:

Lack of assurance of sterility

Recall Number:

D-0132-2019

Code Information:

Lot # 8/8/18 0200 15-21070S, Exp 11/06/2018

Product Description:

Hydromorphone (0.2 mg/mL) in NS 100 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38

Product Quantity:

360 bags

Reason for Recall:

Lack of assurance of sterility

Recall Number:

D-0133-2019

Code Information:

Lot # 8/27/18 0215 22110P, Exp 12/10/2018

Product Description:

Phenylephrine 25 mg added to NS 250 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38

Product Quantity:

300 bags

Reason for Recall:

Lack of assurance of sterility

Recall Number:

D-0134-2019

Code Information:

Lot# 138-20182308@88, Exp 11/06/2018

Product Description:

Phenylephrine 30 mg added to NS 250 mL Bag, Rx only, Advanced Pharma, Inc. d/b/a Avella of Houston, and Avella of Deer Valley, Inc. #38

Product Quantity:

300 bags

Reason for Recall:

Lack of assurance of sterility

Recall Number:

D-0135-2019

Code Information:

Lot# 138-20180409@55, Exp 11/18/2018

Class II Drugs Event

Event ID:
81442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/31/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma Limited (Unit I)
385 386 Bulk Active Plant Unit I; Survey 379
Arutla India

Distribution Pattern:
Product was distributed to one customer in NY.

Associated Products

<p>Product Description: Irbesartan Bulk Active Pharmaceutical Ingredient.</p> <p>Product Quantity: 1724.8 kgs.</p> <p>Reason for Recall: CGMP Deviation: Presence of NDEA (N-Nitrosodimethylamine), a carcinogen impurity, detected in the active ingredient.</p> <p>Recall Number: D-0127-2019</p> <p>Code Information: Manufacturing batch numbers: 1601100782, dispatch batch number 1601101589, exp. date 12/01/2018 1601100783, dispatch batch number 1601101590, exp. date 12/01/2018 1701111861, dispatch batch number 1701113404, exp. date 09/01/2020 1701112170, dispatch batch number 1701113405, exp. date 09/01/2020 1701112501, dispatch batch number 1701113406, exp. date 09/01/2020 1701112056, dispatch batch number 1701113407, exp. date 09/01/2020 1701112558, dispatch batch number 1701114283, exp. date 10/01/2020 1701112559, dispatch batch number 1701114285, exp. date 10/01/2020 1701112589, dispatch batch number 1701114286, exp. date 10/01/2020 1701113300, dispatch batch number 1701114289, exp. date 10/01/2020 1701113301, dispatch batch number 1701114291, exp. date 10/01/2020 1701113302, dispatch batch number 1701114708, exp. date 10/01/2020 1701113312, dispatch batch number 1701114709, exp. date 10/01/2020 1701115460, dispatch batch number 1701117039, exp. date 11/01/2020 1701115974, dispatch batch number 1701117040, exp. date 11/01/2020 1701115460, dispatch batch number 1701117041, exp. date 11/01/2020 1701115738, dispatch batch number 1701117042, exp. date 11/01/2020 1701115739, dispatch batch number 1701117043, exp. date 11/01/2020 1701115740, dispatch batch number 1701117044, exp. date 11/01/2020 1701115741, dispatch batch number 1701117045, exp. date 11/01/2020 1701115742, dispatch batch number 1701117046, exp. date 11/01/2020</p>

Class III Drugs Event

Event ID:
81002

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/01/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pharm D Solutions, LLC
1304 S Loop W
Houston TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:

Calcium Gluconate 2.5% a) 250 mL 25 mg/mL NDC 69699-0908-25; b) Nasal Spray 2.5 Inhal Soln. NDC 69699-0908-10; c) Nebulization Solution 2.5% Inhal. Soln NDC 69699-0908-10; d) Nebulization 250 mL 2.5% Inhal Soln NDC 69699-0908-25; e) Oral Spray 2.5% 2.5% Oral Soln NDC 69699-0917-60, Pharm D Solutions, Houston, Texas

Product Quantity:

57 bottles; 2300 milliliters

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0149-2019

Code Information:

Lots: a) 05072018:40 Discard by: 5/2/2019; b) 07262018:44 Discard by: 1/22/2019; c) 07122018:83 Discard by: 7/12/2019; d) 07262018:93 Discard by: 1/22/2019; e) 07262018:81 Discard by: 1/21/2019