

Enforcement Report - Week of July 25, 2018

Class II Drugs Event

Event ID:

80307

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/12/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

07/19/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Avella of Deer Valley, Inc. Store 38

24416 N 19th Ave

Phoenix AZ United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

0.2% ROPivacaine - OnQ Pump, (ROPivacaine HCL (USP) 1100mg, 0.9% Sodium Chloride (USP) QS 550 ml, single dose pump. For: Vidant Medical Center, By: Avella of Houston, 9265 Kirby Dr., Houston, TX 77056. NDC: 42852-661-02

Product Quantity:

40 pumps

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0928-2018

Code Information:

Lot # 5/14/18 0749 525-66102, BUD 6/13/2018; 5/22/18 0837 495-66102, BUD 6/21/2018

Product Description:

ceFAZolin 2 gm in NS 100mL. ceFAZolin Sodium (USP) 2gm, 0.9% Sodium Chloride (USP) 100mL. Volume 110 mL. Single dose bag. Avella of Houston 9265 Kirby Dr., Houston, TX 77054 NDC: 42852-604-10

Product Quantity:

2,500 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0929-2018

Code Information:

Lot # 4/27/18 2002 60410P, 4/27/18 2030 60410P, BUD 6/26/2018

Product Description:

ePHEDrine 50mg, 50 mg/10 mL (5 mg per mL) (Ephedrine Sulfate, USP 50mg in 0.9% Sodium Chloride, USPQS 10mL. 10 mL-Sterile use dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054 NDC 42852-805-61

Product Quantity:

5400 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0930-2018

Code Information:

Lot # 3/5/18 8055 80561S, 3/5/18 0514 80561S, 3/5/18 5259 80561S, 3/5/18 6131 80561S, 3/5/18 5641 80561S, BUD 7/3/2018; 5/10/18 1312 80561S, 5/10/18 1322 80561S, BUD 9/7/2018;

Product Description:

EPINEPHrine (USP) 4 mg, 5% Dextrose For Inj. (USP) 250 mL Volume: 254 mL single dose bag. For: Peninsular Regional Medical Center. By: Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054. NDC 15082-855-25.

Product Quantity:

420 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0931-2018

Code Information:

Lot # 5/4/18 0300 58-85525P, BUD 6/18/2018; 5/10/18 1435 262-85525P, 5/10/18 1127 558-85525P, BUD 6/24/2018; 5/11/18 1327 457-85525P, BUD 6/25/2018; 5/14/18 0302 295-85525P, BUD 6/28/2018; 5/17/18 0500 558-85525P, BUD 7/1/2018; 5/24/18 1005 57-85525P, 5/24/18 1328 295-85525P, BUD 7/7/2018; 5/25/18 0302 295-85525P, BUD 7/9/2018; 5/30/18 0936 262-85525P, BUD 7/14/2018; 5/31/18 0805 558-85525P, BUD 7/17/2018.

Product Description:

EPINEPHrine (USP) 4 mg, 0.9% Sodium Chloride (USP) 250 mL Volume: 254 mL single dose bag. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-823-25.

Product Quantity:

700 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0932-2018

Code Information:

Lot # 4/30/18 0512 2-82325P, BUD 6/14/2018; 5/22/18 1238 82325P, BUD 7/6/2018.

Product Description:

fentaNYL (10 mcg per mL) in 0.95 Sodium Chloride, USP QS 1mL. Volume 1mL. Single dose Syringe. For: Hunt Regional Medical Center, By: Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054. NDC 15082-210-70

Product Quantity:

120 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0933-2018

Code Information:

Lot # 5/3/18 0317 142-21070S, BUD 8/1/2018; 5/10/18 0512 144-21070S, BUD 8/8/2018; 6/1/18 0305 142-21070S, BUD 8/30/2018; 6/4/18 0505 252-21070S, BUD 9/2/2018.

Product Description:

HEPARIN 25,000 Units in 5% Dextrose (Heparin Sodium, USP 25,000 Units, 5% Dextrose Inj., USP 250 mL) Volume: 255 mL. Single dose bag. Avella Specialty Pharmacy, 24416 N 19th Avenue, Phoenix AZ 85085. NDC 42852-729-25

Product Quantity:

240 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0934-2018

Code Information:

Lot # 138-20181505@92, BUD 8/23/2018; 138-20181605@78, BUD 8/24/2018

Product Description:

HYDROMorphone 1 mg/mL (HYDROMorphone HCL (USP) 50 mg, 0.9% Sodium Chloride (USP) QS 50 mL) Volume: 50mL. Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX. NDC 42852-222-65

Product Quantity:

275 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0935-2018

Code Information:

Lot # 5/16/18 1207 22265S, BUD 8/14/2018.

Product Description:

MAGnesium 4gm in NS 100 mL (MAGnesium SULfate (USP) 4 gm, 0.9% Sodium Chloride (USP) 100 mL). Volume: 108 mL. Single dose bag. For: Gaston Memorial Hospital By: Avella of Houston, 9256 Kirby Dr., Houston, TX 77054. NDC: 42852-905-10

Product Quantity:

100 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0936-2018

Code Information:

Lot # 5/1/18 0501 548-90510P, BUD 7/30/2018.

Product Description:

Midazolam 1 mg/mL (Midazolam HCL (USP) 100 mg, Sodium Chloride, USP QS 100 mL) Volume: 100 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr., Houston TX 77054. NDC 4252-401-10

Product Quantity:

1860 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0937-2018

Code Information:

Lot # 5/7/18 7482 40110P, BUD 9/4/2018; 5/22/18 0804 40110P, BUD 9/19/2018; 5/3/18 1111 40110P, BUD 8/31/2018.

Product Description:

MORphine 1 mg/mL (Morphine Sulfate, USP 100mg, 0.9% Sodium Chloride, USP QS 100 mL). Volume 100 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-241-10

Product Quantity:

1500 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0938-2018

Code Information:

Lot #: 5/15/18 6413 24110P, BUD; 9/12/2018; 5/16/18 0744 24110P, BUD 9/13/2018.

Product Description:

NORepiNEPhrine 8 mg (norepinephrine Bitartrate (USP) 8 mg added to 5% Dextrose Inj. (USP) 250 mL. (Concentration 32 mcg/mL) Volume: 258 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr. Houston, TX 77054. NDC 42852-815-25

Product Quantity:

4,280 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0939-2018

Code Information:

Lot #4/23/18 0101 81525P, 4/23/18 1020 81525P, BUD 6/22/2018;4/30/18 1123 81525P, 4/30/18 1311 81525P, BUD 6/29/2018; 5/1/18 3456 81525P, BUD 6/30/2018; 5/8/18 3213 81525P, BUD 7/7/2018.

Product Description:

PHENYLEphrine 40 mg (PHENYLEphrine HCL (USP) 40 mg, 5%Dextrose Inj., USP 250 mL) Volume: 254 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-893-25

Product Quantity:

200 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0940-2018

Code Information:

Lot # 5/23/18 3812 89325P, BUD 8/6/2018.

Product Description:

Vancomycin 1.25gm in D5W 250 mL. (Vancomycin HCL (USP) 1.25 gm, 5% Dextrose Inj. (USP) 250 mL) Volume: 262 mL. Single dose bag. Avella Specialty Pharmacy, 24416N 19th Avenue, Phoenix, AZ 85085. NDC 42852-617-25

Product Quantity:

1,352 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0941-2018

Code Information:

Lot # 138-20181005@92, 138-20181005@91, 138-20181005@90, BUD 7/9/2018; 138-20181405@78, BUD 7/13/2018; 138-20181605@61, BUD 7/15/2018

Product Description:

0.2% ROPivacaine, (Ropivacaine HCL PF, USP 500mg, 0.9% Sodium Chloride, USP QS 250 mL). Volume 250 mL. Single dose Cassette. For: Parkland Memorial Hospital. By: Advanced Pharma, 9225 Kirby Dr. Houston, TX 77054. Parkland Memorial Hospital NDC 15082-002-87

Product Quantity:

20 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0942-2018

Code Information:

Lot 5/14/18 0722 47-00287Y EXP 06/28/2018

Product Description:

ePHEDrine Sulfate, USP 50mg in 0.9% Sodium Chloride USP QS 10mL. 50 mg/10 mL (5 mg/mL). Volume: 10 mL. Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-891-61

Product Quantity:

500 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0943-2018

Code Information:

Lot #: 05/10/18 2011 89161S, BUD 9/7/2018

Product Description:

fentaNYL 3 mcg/mL, 0.1% Bupivacaine, Fentanyl Citrate, USP 750 mcg, Bupivacaine HCL PF, USP, 250 mg, 0.9% Sodium Chloride, USP QS 250 mL. Volume: 250mL. Single dose Cassette. For: Methodist St. John Hospital, By: Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054. NDC 1508 2-250-87

Product Quantity:

15 cassettes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0944-2018

Code Information:

Lot #: 5/14/18 0913 320-25087Y, BUD 6/28/2018.

Product Description:

fentaNYL 5 mcg Citrate, USP 5 mcg in 0.9% Sodium Chloride, USP QS 0.5mL. (10 mcg per mL) 5 mcg in 0.5 mL. Volume: 0.5 mL. Single dose syringe. For Cook Children's Med Ctr. By: Advanced Pharma, 9265 Kirby Dr., Houston TX 77054. NDC 15082-210-72

Product Quantity:

100 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0945-2018

Code Information:

Lot #: 5/24/18 0502 149-21072S, BUD 8/22/2018.

Product Description:

fentaNYL 2 mcg/mL, 0.125% ROPivacaine, Fentanyl Citrate, USP 300 mcg, Ropivacaine HCL PF, USP 187.5 mg, 0.9% Sodium Chloride, USP QS 150 mL. Volume: 150 mL. Single dose cassette For: Methodist Dallas Medical Center. By: Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054. NDC 15082-278-86

Product Quantity:

100 cassettes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0946-2018

Code Information:

Lot #: 5/14/18 1012 172-27886Y, BUD 6/28/2018.

Product Description:

HEPARIN 12,500 Units in 5% Dextrose. (Heparin Sodium, USP 12,500 Units, 5% Dextrose Inj., USP 250 mL) Volume: 252.5 mL. Single dose bag. Avella Specialty Pharmacy, 24416 N 19th Avenue Phoenix, AZ 85085. NDC 42852-745-25

Product Quantity:

900 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0947-2018

Code Information:

Lot #: 138-20181105@65,138-20181105@64, 138-20181105@63, BUD 8/19/2018.

Product Description:

HEPARIN 1,000 Units in NS 250mL. (Heparin Sodium, USP 1,000 Units, 0.9% Sodium Chloride, USP 250 mL) Volume: 251 mL. Single dose bag. For: Adventist Medical Center Hanford. By: Avella of Huston, 9265 Kirby Dr., Houston TX, 77054. NDC 42852-747-25

Product Quantity:

40 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0948-2018

Code Information:

Lot #: 5/1/18 0511 515-74725P, BUD 7/30/2018.

Product Description:

HYDROMorphone 1 mg/mL (HYDROMorphone HCL (USP) 30 mg, 0.9% Sodium Chloride (USP) QS 30 mL) Volume: 30mL. Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX. NDC 42852-222-63

Product Quantity:

480 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0949-2018

Code Information:

Lot #: 3/15/18 0954 22263M, BUD 6/13/2018.

Product Description:

HYDROMorphone 0.2mg/mL. (Hydromorphone HCL (USP) 20 mg, 0.9% Sodium Chloride (USP) QS 100 mL) Volume: 100mL. Single dose bag. Advanced Pharma, 9265 Kirby Dr., Houston, TX. NDC 15082-221-10

Product Quantity:

660 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0950-2018

Code Information:

Lot #: 4/26/18 0520 22110P, BUD 8/9/2018; 5/14/18 1350 22110P, BUD 8/27/2018.

Product Description:

MAGnesium 1gm in NS 100 mL (MAGnesium SULfate (USP) 1 gm, 0.9% Sodium Chloride (USP) 100 mL). Volume: 102 mL. Single dose bag. For: Salt Lake Regional Med Ctr By: Avella of Houston, 9256 Kirby Dr., Houston, TX 77054. NDC: 42852-906-10

Product Quantity:

25 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0951-2018

Code Information:

Lot #: 5/15/18 0510 169-90610P, BUD 8/13/2018.

Product Description:

MAGnesium 2gm in NS 100 mL (MAGnesium SULfate (USP) 2 gm, 0.9% Sodium Chloride (USP) 100 mL). Volume: 104 mL. Single dose bag. For: Desert Regional Med Ctr By: Avella of Houston, 9256 Kirby Dr., Houston, TX 77054. NDC: 42852-907-10

Product Quantity:

175 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0952-2018

Code Information:

Lot #: 5/2/18 0318 284-90710P, BUD 7/31/2018; 5/9/18 0502 423-90710P, BUD 8/7/2018; 5/18/18 0500 284-90710P, BUD 8/16/2018.

Product Description:

MORphine 1 mg/mL (Morphine Sulfate, USP 250mg, 0.9% Sodium Chloride, USP 250 mL). Volume 255 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-241-25

Product Quantity:

130 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0953-2018

Code Information:

Lot #:2/26/18 0301 24125P, BUD 6/26/2018.

Product Description:

MORphine 150 mg (Morphine Sulfate, USP 150mg in 0.9% Sodium Chloride, USP QS 30mL). Volume 30 mL. Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-243-63

Product Quantity:

740 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0954-2018

Code Information:

Lot #:2/26/18 2233 24363M, BUD 6/26/2018.

Product Description:

Midazolam 1 mg/mL (Midazolam HCL USP 30 mg, 0.9% Sodium Chloride, USP QS 30 mL) Volume: 30 mL. Single dose syringe. For: Methodist Willowbrook Hospital, By: Advanced Pharma, 9265 Kirby Dr., Houston TX 77054. NDC 15082-401-63

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0955-2018

Code Information:

Lot #:5/11/18 1050 28-40163M, BUD 7/25/2018.

Product Description:

Midazolam 0.5mg/mL (Midazolam HCL (USP) 50 mg, 0.9% Sodium Chloride, USP QS 100 mL) Volume: 100 mL. Single dose bag. For: Coral Gables Hospital, By: Advanced Pharma, 9265 Kirby Dr., Houston TX 77054. NDC 15082-408-10

Product Quantity:

220 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0956-2018

Code Information:

Lot #:5/21/18 0506 240-40810P, BUD 8/4/2018; 5/22/18 0501 86-40810P, BUD 8/5/2018; 5/25/18 0900 410-40810P, BUD 8/8/2018; 6/6/18 0836 86-40810P, BUD 8/20/2018.

Product Description:

Midazolam 1 mg/mL (Midazolam HCL (USP) 55 mg, 0.9% Sodium Chloride, (USP) QS 55 mL) Volume: 55mL. Single dose syringe. Advanced Pharma, 9265 Kirby Dr., Houston TX 77054. NDC 15082-401-76

Product Quantity:

110 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0957-2018

Code Information:

Lot #:5/14/18 2011 40176S, BUD 9/11/2018.

Product Description:

NORepiNEPHrine 16 (NORepiNEPHrine Bitartrate (USP) 16 mg, 5% Dextrose Inj. (USP) 250 mL. Volume: 266 mL. Single dose bag. Avella of Houston, 9265 Kirby Dr. Houston, TX 77054. NDC 42852-834-25

Product Quantity:

520 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0958-2018

Code Information:

Lot #:4/26/18 0515 83425P, BUD 6/25/2018; 4/24/18 1332 83425P, BUD 6/23/2018.

Product Description:

NORepiNEPHrine Bitartrate, USP 160 mcg in 5% Dextrose, USP QS 10mL. Volume 10mL. Single dose syringe. Avella of Houston, 9265 Kirby Dr. Houston, TX 77054. NDC 42852-807-61

Product Quantity:

850 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0959-2018

Code Information:

Lot #: 5/7/18 0301 2-80761S, BUD 6/21/2018; 5/9/18 0510 2-80761S, BUD 6/23/2018; 5/21/18 1807 80761S, BUD 7/15/2018.

Product Description:

NORepiNEPHrine4mg (Norepinephrine Bitartrate (USP) 4 mg added to 5% Dextrose Inj. (USP) 250 mL (Concentration 16 mcg/mL) Volume: 254 mL Single dose bag. Avella of Houston, 9265 Kirby Dr. Houston, TX 77054. NDC 42852-807-25

Product Quantity:

2280 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0960-2018

Code Information:

Lot #: 4/30/18 2471 80725P, BUD 6/29/2018; 5/1/18 1240 80725P, BUD 6/30/2018; 5/8/18 1111 80725P BUD 7/7/2018.

Product Description:

NORepiNEPHrine4mg (Norepinephrine Bitartrate (USP) 4 mg added to 0.9% Sodium Chloride (USP) 250 mL Volume: 254 mL Single dose bag. Avella of Houston, 9265 Kirby Dr. Houston, TX 77054. NDC 42852-860-25

Product Quantity:

1290 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0961-2018

Code Information:

Lot #: 5/14/18 1330 86025P, BUD 7/8/2018; 5/24/18 2314 86025P, BUD 7/18/2018. .

Product Description:

PHENYLEphrine 20 mg (PHENYLEphrine HCL (USP) 20 mg, 5% Dextrose (USP) 250 mL) Volume: 252 mL. Single dose bag. For: Vidant Medical Center, By: Avella of Houston, 9265 Kirby Dr., Houston, TX 77054. NDC 42852-894-25

Product Quantity:

120 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0962-2018

Code Information:

Lot #: 5/22/18 1012 495-89425P, BUD 7/21/2018; 6/5/18 0302 495-89425P, BUD 8/4/2018. .

Product Description:

ePHEDrine Sulfate, USP 25 mg in 0.9% Sodium Chloride, USP QS 5mL. Volume 5 mL Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054 NDC 42852-805-67

Product Quantity:

10500 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0963-2018

Code Information:

Lot #: 3/5/18 6702 80567S, 3/5/18 2119 80567S, BUD 7/3/2018; 4/30/18 3701 80567S, BUD 8/28/2018; 5/10/18 3333 80567S, 5/10/18 2222 80567S, 5/10/18 1111 80567S, BUD 9/7/2018. .

Product Description:

ePHEDrine Sulfate, USP 50 mg in 0.9% Sodium Chloride, USP QS 10mL. 50 mg/10 mL (5 mg per mL). Volume 10 mL Single dose syringe. Avella of Houston, 9265 Kirby Dr., Houston, TX 77054 NDC 42852-895-61

Product Quantity:

225 syringes

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0964-2018

Code Information:

Lot #: 5/10/18 1451 89561S, BUD 9/7/2018. .

Product Description:

PHENYLEphrine 10 mg (PHENYLEphrine HCL (USP) 10mg, 0.9% Sodium Chloride (USP) 250 mL. Volume: 251 mL Single dose bag. For: Redlands Community Hospital Pharmacy. BY: Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 NDC 15082-856-25

Product Quantity:

40 bags

Reason for Recall:

Lack of Assurance of Sterility: Potential leakage of bags.

Recall Number:

D-0965-2018

Code Information:

Lot #: 4/30/18 0732 558-85625P, BUD 6/29/2018. .

Class II Drugs Event

Event ID:

80416

Product Type:

Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/13/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
La Vita Compounding Pharmacy, LLC
3978 Sorrento Valley Blvd Ste 300
San Diego CA United States

Distribution Pattern:
Product was distributed to patients via patient specific prescription only in CA.

Associated Products

Product Description:
Methylcobalamin 1mg/mL Injection w/Pres. (Benzyl Alcohol 1% in Sterile Water), packaged in 10 mL and 30 mL vials, Rx only, la VITA Compounding Pharmacy, 858.453.2500

Product Quantity:
19,040 mL total dispensed in 10 mL and 30 mL vials

Reason for Recall:
Lack of Processing Controls: products produced in a manner that calls into question the sterility of the drug product intended to be sterile.

Recall Number:
D-0921-2018

Code Information:
Lot #s: 139140@3, Exp 07/23/2018; 141106@1, Exp 08/21/2018; 142919@13, Exp 09/17/2018; 143291@6, Exp 09/23/2018; 145701@3, Exp 10/29/2018; 146932@3, Exp 11/19/2018

Product Description:
Methyl Folate CA+ 1mg/ml Injection w/Pres. (Benzyl Alcohol 1% in Sterile Water), 10 mL and 30 mL vials, Rx only, la VITA Compounding Pharmacy, 858.453.2500

Product Quantity:
17,610 mL total dispensed in 10 mL and 30 mL vials

Reason for Recall:
Lack of Processing Controls: products produced in a manner that calls into question the sterility of the drug product intended to be sterile.

Recall Number:
D-0922-2018

Code Information:
Lot #: 140089@1, Exp 08/06/2018; 141968@6, Exp 09/03/2018; 143381@2, Exp 09/24/2018; 145265@13, Exp 10/22/2018; 146479@6, Exp 11/12/2018

Product Description:
Glutathione 200mg/mL Injection w/Pres. (Benzyl Alcohol 1.5% in Sterile Water), 30 mL vial, Rx only, la VITA Compounding Pharmacy, 858.453.2500

Product Quantity:
191 vials

Reason for Recall:
Lack of Processing Controls: products produced in a manner that calls into question the sterility of the drug product intended to be sterile.

Recall Number:
D-0923-2018

Code Information:
Lot #: 144326@3, Exp 07/10/2018; 145953@2, Exp 08/05/2018

Class II Drugs Event

Event ID:
80440

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/13/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
AZ

Associated Products

Product Description: Metformin Hydrochloride Extended Release Tablets, USP, 500 mg, packaged in a 500-count bottle, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389 350 Gujarat. India, NDC 6 2756-142-02
Product Quantity: 2508 bottles
Reason for Recall: Presence of foreign substance: One lot of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg (500 Count) contains foreign matter identified as a piece of rubber glove detected in one tablet.
Recall Number: D-0924-2018
Code Information: Lot #: JKT0042A, Exp 1/2021

Class II Drugs Event

Event ID:
80473

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/13/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Hain Celestial Group, Inc. - Worldwide HQ
1111 Marcus Ave
New Hyde Park NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description: alba BOTANICA sport mineral sunscreen (titanium dioxide 7.0% and zinc oxide 9.0%), spf 45, 170 g (6 oz) tubes packaged in a) 4 tubes per case; b) 8 pack shipper display; Manufactured By: The Hain Celestial Group, Inc., Lake Success, NY 11042, UPC 7 24742 01102 4.
Product Quantity: 47,128 tubes

Reason for Recall:

Incorrect Product Formulation: wrong sunscreen product in the package.

Recall Number:

D-0920-2018

Code Information:

Lot Codes: a) 7363B, 7363I, 8002C, 8002I, 8054J, 8055B, 8174A; and b) 7353