

Enforcement Report - Week of October 30, 2019

Class II Drugs Event

Event ID:

83833

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/18/2019

Voluntary / Mandated:**Center Classification Date:**

10/18/2019

Initial Firm Notification of Consignee or Public:**Recalling Firm:**

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

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Povidone Iodine, 5% Ophthalmic Solution, 5 mL per droptainer, Repackaged by: Avella Specialty Pharmacy, 24416 N. 19th Ave., Phoenix, AZ 85085. NDC 42852-006-20

Product Quantity:

808 droptainers

Reason for Recall:

Lack of sterility assurance.

Recall Number:

D-0152-2020

Code Information:

Lot #: 138-20190205@3, Exp . Date 10/29/2019; 138-20190705@7, Exp. Date 11/3/2019

Class II Drugs Event

Event ID:

83999

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/09/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/18/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:

Nationwide.

Associated Products

Product Description:

Amino Acid Injection 50 g/1000 mL (50 mg/mL) 25 g L-Arginine HCl; 25 g L-Lysine HCl, Single Dose Container, Rx Only Nephron 503B outsourcing facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-988-10

Product Quantity:

162 bags

Reason for Recall:

Lack of Assurance of Sterility; bags have potential to leak

Recall Number:

D-0150-2020

Code Information:

Lots: AA9023A Exp. 10/24/2019; AA9023B Exp. 10/24/2019

Product Description:

del Nido Cardioplegia Solution, 1000 mL, Single-Dose Container, Rx Only Nephron 503B Outsourcing Facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-984-10

Product Quantity:

1047 bags

Reason for Recall:

Lack of Assurance of Sterility; bags have potential to leak

Recall Number:

D-0151-2020

Code Information:

Lots: NC9048A Exp. 10/14/2019; NC9048B Exp. 10/14/2019; NC9049A Exp. 10/16/2019; NC9049B Exp. 10/16/2019; NC9051A Exp. 10/21/2019; NC9051B Exp. 10/21/2019; NC9052A Exp. 10/22/2019; NC9052B Exp. 10/22/2019; NC9053A Exp. 10/23/2019; NC9053B Exp. 10/23/2019; NC9054A Exp. 10/28/2019; NC9054B Exp. 10/28/2019; NC9055A Exp. 10/30/2019; NC9056B Exp. 11/04/2019

Class II Drugs Event

Event ID:

84000

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/09/2019

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/18/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Nephron Pharmaceuticals Corporation dba Nephron Sterile Compounding Center
4500 12th Street Ext
West Columbia SC United States

Distribution Pattern:

Nationwide.

Associated Products

Product Description:

PF-Fentanyl Citrate (2 mcg/mL)* & Bupivacaine HCl 0.0625 in 0.9% Sodium Chloride Injection-250 mL Total Dose: (500 mcg/156.3 mg)/250 mL, Rx Only, Nephron 503B Outsourcing Facility 4500 12th St. Extension West Columbia, SC 29172 NDC 69374-0525-25

Product Quantity:

1855 bags

Reason for Recall:

GMP Deviations: potential glass contamination

Recall Number:

D-0147-2020

Code Information:

Lots: FB9001 A Exp. 10/31/2019, FB9001B Exp. 10/31/2019; FB9013A Exp. 12/08/2019; FB9015A Exp. 12/14/2019

Product Description:

PF-Fentanyl Citrate 2 mcg/mL* & Bupivacaine HCl 0.125% in 0.9% Sodium Chloride Injection-250 mL, Rx Only Total Dose: (500 mcg/312.5 mg)/250 mL, Nephron 503B Outsourcing Facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-530-25

Product Quantity:

1370 bags

Reason for Recall:

GMP Deviations: potential glass contamination

Recall Number:

D-0148-2020

Code Information:

Lots: FB9014A Exp. 12/09/2019; FB9017A Exp. 12/16/2019

Product Description:

PF-Fentanyl Citrate 2 mcg/mL* & Ropivacaine HCl 0.1% in 0.9% Sodium Chloride Injection-200 mL Total Dose: (400 mcg/200 mg)/200 mL, Rx Only Nephron 503B Outsourcing Facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-526-20

Product Quantity:

615 bags

Reason for Recall:

GMP Deviations: potential glass contamination

Recall Number:

D-0149-2020

Code Information:

Lot: FR9002A Exp. 12/12/2019