

Enforcement Report - Week of July 10, 2019

Class III Drugs Event

Event ID:

83137

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

09/25/2017

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

07/01/2019

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amneal Pharmaceuticals, Inc.
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Esterified Estrogens & Methyltestosterone Tablets, USP 0.625 mg/1.25 mg, 100-count bottles, Rx Only, Manufactured by: Amneal Pharmaceuticals of NY Hauppauge, NY 11788 Distributed by: Seton Pharmaceuticals Manasquan, NJ 08736, NDC 13925-171-01

Product Quantity:

19104 units

Reason for Recall:

Subpotent Drug: Out of specification assay result in Esterified Estrogen and Methyltestosterone tablets.

Recall Number:

D-1438-2019

Code Information:

Lot #: HL05715, HL05815, Exp. 11/2017

Product Description:

Esterified Estrogens & Methyltestosterone Tablets, USP 1.25 mg/2.5 mg, 100-count bottles, Rx Only, Manufactured by: Amneal Pharmaceuticals of NY Hauppauge, NY 11788 Distributed by: Seton Pharmaceuticals Manasquan, NJ 08736, NDC 13925-172-01

Product Quantity:

19176 units

Reason for Recall:

Subpotent Drug: Out of specification assay result in Esterified Estrogen and Methyltestosterone tablets.

Recall Number:

D-1439-2019

Code Information:

Lot #: HL06015, HL06115, Exp. 10/2017

Not Yet Classified Drugs Event

Event ID:

83207

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

06/07/2019

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

PharMEDium Services, LLC
36 Stults Rd
Dayton NJ United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Hydromorphone HCL in 0.9% sodium chloride, 0.5mg per mL, 1 mL in 3mL BD Syringe, PharMEDium 913 N Davis Ave Cleveland, MS 38732, 800-523-7749, NDC 61553-352-78

Product Quantity:

28,140 syringes

Reason for Recall:

Incorrect/Undeclared Excipients: Product listed as sulfite free but contains hydromorphone contains sulfite

Recall Number:

Code Information:

Lot #: 190670030D, 190670031D, 190670032D, 190670033D, Exp. 6/9/2019; 190710015D, 190710016D, 190710017D, 190710018D, 190710019D, Exp. 6/11/2019; 190730028D, 190730029D, 190730030D, Exp. 6/13/2019; 190740018D, Exp.6/16/2019; 190770028D, 190770029D, Exp. 6/17/2019; 190780027D, 190780028D, 190780029D, Exp. 6/18/2019; 190790030D, Exp. 6/19/2019; 190800012D, 190800013D, 190800014D, 190800015D, 190800016D, Exp.6/20/2019; 190810033D, 190810034D, 190810035D, 190810036D, Exp.6/23/2019; 190840002D, Exp. 6/24/2019; 190870008D, Exp. 6/27/2019; 190910015D, Exp. 7/1/2019; 190980033D, Exp. 7/8/2019; 190990017D, 190990030D, Exp. 7/9/2019; 191000035D, Exp. 7/10/2019; 191010008D, 191010009D, 191010010D, Exp. 7/11/2019; 191050002D, Exp.7/15/2019; 191120002D, Exp.7/22/2019; 191160001D, Exp. 7/28/2019; 191210020D, 191210021D, 191210022D, Exp.7/31/2019; 191220017D, Exp.8/1/2019.