Enforcement Report - Week of July 26, 2017

Class II Drugs Event

Event ID:
77634

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/14/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
PharMedium Services, Llc
12620 W Airport Blvd Ste 130
Sugar Land TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Succinylcholine Chloride Injection (Preserved) 20 mg per mL, 200 mg per 10 mL, 10 mL Total Volume in BD Syringe, For IV Use, PharMedium Services, LLC, Cleveland, MS --- NDC 61553-364-65

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0985-2017

Code Information:
Lots: 171390026D Exp. 08/20/2017; 171370064D Exp. 8/16/2017; 171390027D Exp. 8/20/2017; 171420074D Exp. 8/21/2017; 171430062D Exp. 8/22/2017; 171440058D Exp. 8/23/2017; 171450001D Exp. 8/23/2017; 171450002D Exp. 8/23/2017; 171450056D Exp. 08/24/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 10 mMol in a) 100 mL in 150 mL Intravia Bag (NDC 61553-288-48) Service Code: 2K5288, and b) 250 mL in 250 mL Intravia Bag (NDC 61553-281-11) Service Code: 2K5281, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0986-2017

Code Information:
Lots: a) 171280006S Exp. 8/6/2017; 171280125S Exp. 8/7/2017; 171290006S Exp. 8/7/2017; 171290028D Exp. 8/8/2017; 171360002S Exp. 8/15/2017; b) 171280011S Exp. 8/7/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection 15 mMol in a) 100 mL in 150 mL Intravia Bag Service Code 2K5295 NDC# 61553-295-48; b) 150 mL in 150 mL Intravia Bag Service Code 2K5292 NDC# 61553-292-01; c) 250 mL in 250 mL Intravia Bag Service Code 2K5282 NDC# 61553-282-11; d) 250 mL in 250 mL Intravia Bag with Additive Cap Service Code 2K5291 NDC# 61553-291-11, Rx Only PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0987-2017

Code Information:
Lots: a) 171320006S Exp. 8/13/2017, 171320014D Exp. 8/13/2017,171360020D Exp. 8/15/2017, 171520063D Exp. 8/31/2017; b) 171280054D Exp. 8/7/2017, 171320002D Exp. 8/10/2017, 171370005S Exp. 8/15/2017, 171440016D Exp. 8/23/2017, 171450012D Exp. 8/24/2017, 171510059D Exp. 8/30/2017, 171560027D Exp. 9/4/2017; c) 171170014S Exp. 7/27/2017, 171210127S Exp. 7/31/2017, 171230071D Exp. 8/2/2017, 171240002D Exp. 8/3/2017, 171240004D Exp. 8/3/2017, 171240191S Exp. 8/3/2017, 171280041D Exp. 8/7/2017, 171290077D Exp. 8/8/2017, 171300076D Exp. 8/9/2017, 171310058D Exp. 8/10/2017, 171320059D Exp. 8/13/2017, 171320190S Exp. 8/13/2017, 171360062D Exp. 8/15/2017, 171360068D Exp. 8/15/20

17, 171380076D Exp. 8/17/2017, 171390064D Exp. 8/20/2017, 171390065D Exp. 8/20/2017, 171500064D Exp. 8/29/2017, 171530101S Exp. 9/3/2017, 171570058D Exp. 9/5/2017; d) 171210005S Exp. 7/30/2017, 171230008D Exp. 8/2/2017, 171500072D Exp. 8/29/2017, 171560028D Exp. 9/4/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection 20 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5287 NDC# 61553-287-48

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0988-2017

Code Information:
Lot: 171320001D, 8/10/2017

Product Description:
Potassium PHOSphate in 5% Dextrose Injection, 30 mMol 500 mL in 500 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5283 NDC# 61553-283-03

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0989-2017

Code Information:
Lot: 171350099S, 8/14/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 40 mMol in 250 mL in 250 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5301 NDC# 61553-301-11

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0990-2017

Code Information:
Lots: 171220007S Exp. 7/31/2017, 171280129S Exp. 8/7/2017, 171320112S Exp. 8/13/2017, 171590010S Exp. 9/7/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 7 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5284 NDC# 61553-284-48

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0991-2017

Code Information:
Lots: 171220061D Exp. 8/1/2017, 171250023D Exp. 8/6/2017, 171430008D Exp. 8/22/2017, 171450015D Exp. 8/24/2017, 171510062D Exp. 8/30/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 7.5 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5298 NDC# 61553-298-48NDC# 61553-298-48

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0992-2017

Code Information:
Lots: 171210102S Exp. 7/31/2017, 171320109S Exp. 8/13/2017, 171560012S Exp. 9/4/2017

Product Description:
Potassium PHOSphate in 5% Dextrose Injection, 7.5 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5299 NDC# 61553-299-48

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0993-2017

Code Information:
Lot: 171450017D, 8/24/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 9 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5286 NDC# 61553-286-48

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0994-2017

Code Information:
Lot: 171520062D, 8/31/2017

Product Description:
Potassium PHOSphate in 5% Dextrose Injection, 9 mMol in 50 mL in 50 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5310 NDC# 61553-310-41

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0995-2017

Code Information:
Lots: 171160002S Exp. 7/26/2017, 171560007S Exp. 9/4/2017

Product Description:
Potassium PHOSphate in 0.9% Sodium Chloride Injection, 30 mMol in a) 250 mL in 250 mL Intravia Bag Service Code 2K5290 NDC# 61553-290-11, b) 500 mL in 500 mL Intravia Bag Service Code 2K5285 NDC# 61553-285-03, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0996-2017

Code Information:
Lots: a) 171180027S Exp. 7/29/2017, 171220058D Exp. 8/1/2017, 171230013S Exp. 8/2/2017, 171360008S Exp. 8/14/2017, 171360019D Exp. 8/15/2017, 171380085D Exp. 8/17/2017, 171430069D Exp. 8/22/2017, 171560025D Exp. 9/4/2017; b) 171240007S Exp. 8/3/2017, 171280055D Exp. 8/7/2017, 171320003D Exp. 8/10/2017, 171320008S Exp. 8/13/2017, 171360005S Exp. 8/14/2017, 171370011S Exp. 8/16/2017, 171380086D Exp. 8/17/2017, 171500071D Exp. 8/29/2017

Product Description:
Potassium PHOSphate in 5% Dextrose Injection, 15 mMol in 250 mL in 250 mL Intravia Bag Service, Rx Only. PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5300 NDC# 61553-300-11

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility; media fill failure at manufacturer

Recall Number:
D-0997-2017

Code Information:
Lot: 171420030D, 8/21/2017

Class III Drugs Event

Event ID:
77605

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shionogi Inc.
5770 Shiloh Rd
Alpharetta GA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Mefenamic Acid, 250mg capsules, packaged in 30-count bottles, Rx Only, Distributed by: Prasco Laboratories Mason, OH 45040 USA, Manufactured by: Halo Pharmaceutical Inc. Whippany, NJ 07981, NDC 66993-070-30

Product Quantity:
6304 bottles

Reason for Recall:
Failed Dissolution Specifications: Low dissolution results were obtained during stability testing

Recall Number:
D-0981-2017

Code Information:
Lot #: 5H66200103G, Exp. June 2018; 7H66200103G, Exp. Dec 2019

Product Description:
PONSTEL (Mefanamic Acid) USP, 250 mg capsules, 30-count bottles, Rx Only, Manufactured for: Shionogi Inc. Florham Park, NJ 07932 Manufactured by: Halo Pharmaceutical Inc. Whippany, NJ 07981

Product Quantity:
455 bottles

Reason for Recall:
Failed Dissolution Specifications: Low dissolution results were obtained during stability testing

Recall Number:
D-0982-2017

Code Information:
Lot #: 5H66200103, Exp. June 2018

Class III Drugs Event

Event ID:
77659

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Valeant Pharmaceuticals North America LLC
400 Somerset Corporate Blvd
Bridgewater NJ United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Obagi-C Rx System C-Therapy Night Cream, Net wt. 2 oz. (57g) bottle, Rx only, Distributed by OMP, Inc., Long Beach, CA Made in USA, NDC 62032-222-02

Product Quantity:
844 bottles

Reason for Recall:
Labeling: Incorrect or Missing Package Insert - Obagi-C Rx System C-Therapy Night Cream is being recalled due to incomplete packaging/labeling. The bottle is missing the product insert and outer carton which contain the complete instruction for use and safety information.

Recall Number:
D-0998-2017

Code Information:
Lot #: 2578400, 0Exp 8/2019

Class III Drugs Event

Event ID:
77687

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hospira Inc., A Pfizer Company
275 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Argatroban Injection, 250 mg/2.5 mL (100 mg/mL), 5 mL Single-use vial, Rx Only, Sterile, Manufactured by: Gland Pharma Limited, Hyderabad, India, Manufactured for: Hospira, Inc, Lake Forest, IL 60045 --- NDC 0409-1140-01

Product Quantity:
701 vials

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification result for denitroquinoline-related impurity during three month time point

Recall Number:
D-0980-2017

Code Information:
Lot: DP601, exp 10/2018

Class III Drugs Event

Event ID:
77725

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/14/2017

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 USA

Associated Products

Product Description:
Buprenorphine and Naloxone Sublingual Tablets, 2 mg/0.5 mg 30 tablets per bottle, Rx only, Distributed by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-5720-56

Product Quantity:
25264 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification test results for related compounds largest unknown impurity.

Recall Number:
D-0983-2017

Code Information:
Lot #: 30227613A, 30227614A, 30227615A, EXP 6/2017; 30228559A, 30228560A, EXP 9/2017; 3000123, EXP 7/2018

Product Description:
Buprenorphine and Naloxone Sublingual Tablets 8 mg/2 mg 30 tablets per Bottle, Rx only, Distributed By: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-5721-56

Product Quantity:
196275 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification test results for related compounds largest unknown impurity.

Recall Number:
D-0984-2017

Code Information:
Lot #: 30227649A ,30227650A, 30227651A, 30227652A, 30227653A, 30227654A, 30227655A, 30227832A, 30227833A, 30227834A, 30227835A, E