Class I Drugs Event

Event ID:
76678
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
12/29/2015
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/13/2017
Initial Firm Notification of Consignee or Public:
E-Mail
Recalling Firm:
Complete Pharmacy and Medical Solutions LLC
5829 Nw 158th St
Miami Lakes FL United States
Distribution Pattern:
Distributed throughout Florida

Associated Products

Product Description:
Human Chorionic Gonadotropin, 125 IU HCG, in 0.5 ml syringe, subcutaneous administration, Rx only, Complete Pharmacy & Medical Solutions, Miami Lakes, FL 33014
Product Quantity:
1890 syringes
Reason for Recall:
Non-sterility: presence of mold confirmed by outside laboratory at the 14 day culture.
Recall Number:
D-0917-2017
Code Information:
Lot # 2079ps5, Exp 02/01/2016

Class I Drugs Event

Event ID:
76681
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/02/2016
Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/13/2017
Initial Firm Notification of Consignee or Public:
E-Mail
Recalling Firm:
Complete Pharmacy and Medical Solutions LLC
5829 NW 158th St
Miami Lakes FL United States
Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Human Chorionic Gonadotropin, 15,000 IU per vial, lyophilized for injection, Rx only, Complete Pharmacy & Medical Solutions, Miami Lakes, FL 33014
Product Quantity:
49 vials
Reason for Recall:
Non-sterility - presence of bacteria confirmed by outside laboratory after day 14.
Recall Number:
D-0918-2017
Code Information:
Lot # 22016, Exp 1/30/2017

Class II Drugs Event

Event ID:
74822
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
07/07/2016
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/12/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Safecor Health, LLC
317 New Boston St
Woburn MA United States
Distribution Pattern:
MA and NY

Associated Products

Product Description:
Acetaminophen 325mg tablets, 120-count bottles, Pk By Safecor Health Woburn, MA 01801, NDC 00904198280.
Product Quantity:
66 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0900-2017
Code Information:
Lot #: A18688, Exp. 09/30/2018

Product Description:
Atorvastatin Calcium 40mg Tablet, 30-count bottles, Rx only, Pk By Safecor Health Woburn, MA 01801, NDC 60505258009
Product Quantity:
119 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0901-2017
Code Information:
Lot # A18661, Exp. 10/31/2017

Product Description:
Calcium Carbonate 600mg/Vitamin D3 400 International Units tablets, 60-count bottles, Pk By Safecor Health Woburn, MA 01801, NDC 00904323392.
Product Quantity:
25 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0902-2017
Code Information:
Lot # A18705, Exp. 09/30/2017

Product Description:
Acyclovir 400mg Tablet, 15-count bottles, Rx only, Packaged by Safecor Health, LLC. Woburn, MA 01801, NDC 0093894305
Product Quantity:
601 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0903-2017
Code Information:
Lot # A25591, Exp. 02/22/2017

Product Description:
Doxycycline100mg Tablets, 14-count bottles, Rx only, Packaged By Safecor Health LLC Woburn, MA 01801, NDC 0143314205

Product Quantity:
856 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0904-2017
Code Information:
Lot # A25593, Exp. 2/22/2017

Product Description:
Metronidazole 500mg Tablet, 50-count bottles, Rx only, Packaged By Safecor Health LLC Woburn, MA 01801, NDC 5011133402
Product Quantity:
1,933 bottles
Reason for Recall:
CGMP Deviations
Recall Number:
D-0905-2017
Code Information:
Lot # A25593, Exp. 02/22/2017

Class II Drugs Event

Event ID:
77191
Product Type:
Drugs
Status:
Terminated
Date Terminated:
06/13/2017
Recall Initiation Date:
02/17/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/12/2017
Initial Firm Notification of Consignee or Public:
Telephone
Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States
Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Potassium PHOSphate in 0.5% Dextrose, 7.5 mMol in 100 mL, Service Code 2K5299, NDC#

61553-0299-48, Total Volume 100.00 mL incorrectly labeled as 150.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
144 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0908-2017
Code Information:
Lot Numbers: 170020074D, 4/3/2017; 170050071D, 4/6/2017; 170270036D, 4/30/2017

Product Description:
VANCOMYCIN HCl 1.5g in 300 mL 0.9% Sodium Chloride Injection USP, Service Code 2K2243, NDC# 61553-043-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
816 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0914-2017
Code Information:
Lot Numbers: 170200039S, 2/22/2017; 170230182S, 170230137S, 2/23/2017; 170260122S, 2/26/2017; 170300085S, 3/2/2017; 170320048S, 3/4/2017; 170340152S, 3/8/2017; 170380097S, 3/10/2017

Product Description:
VANCOMYCIN HCl 1.75g in 300 mL 0.9% Sodium Chloride Injection USP, Service Code 2K2237, NDC# 61553-037-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
60 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0915-2017
Code Information:
Lot Numbers: 170160016S, 2/20/2017; 170240147S, 3/1/2017; 170380016S, 3/15/2017; 170450010S, 3/22/2017

Product Description:
VANCOMYCIN HCl 1.5g in 300 mL 5% Dextrose Injection USP, Service Code 2K2227, NDC# 61553-027-34, Total Volume 300.00 mL incorrectly labeled as 500.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
108 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0916-2017

Code Information:
Lot Numbers: 170250124S, 2/25/2017; 170270018S, 2/28/2017; 170380015S, 3/10/2017

Class II Drugs Event

Event ID:
77288
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/18/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/09/2017
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, Canada and Singapore

Associated Products

Product Description:
Levophed norepinephrine bitartrate, injection, USP, 4 mg /4 mL (1 mg/mL),Rx only, Hospira, Inc. Lake Forest, IL --- NDC 0409-3375-04
Product Quantity:
(720503A): 43,200 vials, (720603A): 400 vials
Reason for Recall:
GMP Deviation; A foreign stopper was observed during packaging of a lot of product.
Recall Number:
D-0898-2017
Code Information:
720503A, 720603A (Canada only)

Class II Drugs Event

Event ID:
77391
Product Type:
Drugs
Status:
Ongoing

Date Terminated:
Recall Initiation Date:
06/06/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/09/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Bausch & Lomb, Inc.
8500 Hidden River Pkwy
Tampa FL United States
Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
NasalCrom (cromolyn sodium) Nasal Spray, USP, 5.2 mg per spray, 200 metered sprays, 0.88 FL OZ (26 mL) metered spray pump bottle, Distributed by: Medtech Products, Inc., Tarrytown, NY 10591, UPC 8 148332 01101 7.
Product Quantity:
44,520 bottles
Reason for Recall:
CGMP Deviations: Possibility of the presence of microbial contamination in the water used to manufacture this product lot.
Recall Number:
D-0899-2017
Code Information:
Lot: 253211, Exp 12/18

Class II Drugs Event

Event ID:
77465
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/17/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/15/2017
Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
American Pharmaceutical Ingredients LLC
6650 Highland Rd Ste 302
Waterford MI United States
Distribution Pattern:
NY, GA, NV, CA, KY, TX

Associated Products

Product Description:
ESTRONE USP, packaged in a) 1g bottle (NDC: 58597-8049-2), c) 5g bottle (NDC: 58597-8049-3), d) 25g bottle (NDC: 58597-8049-4), For Prescription Compounding, RX Only, Packed under cGMP conditions by American Pharmaceutical Ingredients, LLC, 6650 Highland Road, Waterford, MI 48327
Product Quantity:
1g=1 bottle; 5g=4 bottle; 25g=3 bottles
Reason for Recall:
cGMP Deviations; lack of quality assurance.
Recall Number:
D-0919-2017
Code Information:
Lots: 052915-1, 052915-2, exp 5/5/2017

Class III Drugs Event
Event ID:
77191
Product Type:
Drugs
Status:
Terminated
Date Terminated:
06/13/2017
Recall Initiation Date:
02/17/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/12/2017
Initial Firm Notification of Consignee or Public:
Telephone
Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States
Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Potassium CHLORide added to 0.9% Sodium Chloride, 30mEq 100 mL Bag, Service Code 2K5824, NDC# 61553-0824-48, Total Volume 100.00 mL incorrectly labeled as 115.00 mL, Rx Only, PharMEDium Services, LLC, 6100 Global Drive, Memphis, TN 38141
Product Quantity:
216 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0906-2017
Code Information:
Lot Numbers: 70090135M, 2/27/2017; 170250101M, 3/15/2017; 170030011D, 4/4/2017; 17004 0078D, 4/5/2017; 170310012D, 5/2/2017; 170400046D, 5/11/2017;

Product Description:
Potassium CHLORide added to 0.9% Sodium Chloride, 10mEq 100 mL Bag, Service Code 2K5856, NDC# 61553-0856-48, Total Volume 100.00 mL incorrectly labeled as 105.00 mL, Rx Only, PharMEDium Services, LLC, 6100 Global Drive, Memphis, TN 38141
Product Quantity:
143 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0907-2017
Code Information:
Lot Numbers: 163640167M, 3/21/2017; 170050171M, 3/28/2017; 170070172M, 3/31/2017;1701 90235M, 4/11/2017; 170200120M, 4/14/2017; 170230115M, 4/15/2017; 170390059D, 5/10/201 7;

Product Description:
Potassium PHOSphate added to 0.9% Sodium Chloride, 7.5 mMol 100 mL Bag, Service Code 2K5298, NDC# 61553-0298-48, Total Volume 100.00 mL incorrectly labeled as 102.50 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
192 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0909-2017
Code Information:
Lot Numbers: 163640146S, 3/30/2017; 170020187S, 4/3/2017; 170100120S, 4/11/2017; 17020 0117S, 4/23/2017; 170340009S, 5/6/2017

Product Description:
Potassium PHOSphate added to 0.9% Sodium Chloride, 15 mMol 100 mL Bag, Service Code 2K5295, NDC# 61553-0295-48, Total Volume 100.00 mL incorrectly labeled as105.00 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
912 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.

Recall Number:
D-0910-2017
Code Information:
Lot Numbers: 170050001D, 4/5/2017; 170040025D, 4/5/2017; 170060046D, 4/9/2017; 1700900 62D, 4/10/2017; 170110125S, 4/12/2017; 170170016S, 4/18/2017; 170200120S, 4/23/2017; 17 0380108S, 5/9/2017;

Product Description:
Potassium PHOSphate added to 0.9% Sodium Chloride, 10 mMol 100 mL Bag, Service Code 2K5288, NDC# 61553-0288-48, Total Volume 100.00 mL incorrectly labeled as 103.33 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
672 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0911-2017
Code Information:
Lot Numbers: 163640076D, 3/30/2017; 170040009D, 4/5/2017; 170040224S, 4/5/2017; 170040 065S, 4/5/2017; 170050068D, 4/6/2017; 170060353S, 4/9/2017; 170100076D, 4/11/2017; 1701 00111S, 4/11/2017; 170120090D, 4/13/2017; 170120154S, 4/13/2017; 170160150S, 4/17/2017; 170260005D, 4/27/2017; 170380110S, 5/9/2017; 170400085S, 5/11/2017

Product Description:
Potassium PHOSphate added to 0.9% Sodium Chloride, 20 mMol 100 mL Bag, Service Code 2K5287, NDC# 61553-0287-48, Total Volume 100.00 mL incorrectly labeled as106.67 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
48 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0912-2017
Code Information:
Lot Numbers: 170100124S, 4/11/2017; 170390015S, 5/10/2017

Product Description:
Potassium PHOSphate added to 0.9% Sodium Chloride, 7 mMol 100 mL Bag, Service Code 2K5284, NDC# 61553-0284-48, Total Volume 100.00 mL incorrectly labeled as 102.33 mL, Rx Only, PharMEDium Services, LLC, 12620 W. Airport Blvd #130, Sugar Land, TX 74478
Product Quantity:
216 bags
Reason for Recall:
Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.
Recall Number:
D-0913-2017
Code Information:
Lot Numbers: 163640084D, 3/30/2017; 170120081D, 4/13/2017; 170160062D, 4/17/2017; 1702 00066D, 4/23/2017; 170370011D, 5/8/2017

Class III Drugs Event

Event ID:
77430
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/09/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/15/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Montelukast Sodium Oral Granules, 4 mg pouch, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV --- NDC 0378-6040-93
Product Quantity:
11,624 pouches
Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification results for Sulphoxide Impurity and Total Impurities
Recall Number:
D-0920-2017
Code Information:
Batch 3074707, exp 02/2018