Enforcement Report - Week of August 29, 2018

Class II Drugs Event

Event ID:
80748

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/18/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
A-S Medication Solutions LLC.
2401 Commerce Dr
Libertyville IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Valsartan Tablets, 160 MG, 30-count bottle (NDC 54569-6583-0), 90-count bottle (NDC 54569-6583-1), Rx Only, MFG: Zhejiang Huahai Pharma, Linhai, Zhejiang 317024 China

Product Quantity:
666 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1108-2018

Code Information:
Expiry, lot: [30-count] 2/28/2019: 7285177; 3/31/2019: 7222163, 7227175; 8/31/2019: 8162190, 8183227. [90-count] 2/28/2019: 7207135, 7212280, 7215073; 3/31/2019: 7222162; 8/31/2019: 8095248, 8095249

Product Description:
Valsartan Tablets, 80 MG, 30-count bottle (NDC 54569-6582-0, 90-count bottle (NDC 54569-6582-1), Rx Only, MFG: Zhejiang Huahai Pharma, Linhai, Zhejiang 317024 China

Product Quantity:
178 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1109-2018

Code Information:
Expiry, lot: [30-count] 11/30/2018: 7258177, 7276228; 2/28/2019: 7212260; [90-count] 11/30/2018: 7208140; 2/28/2019: 7212261, 7221155, 7222161; 8/31/2019: 8109171; 9/30/2019: 8109170

Product Description:
Valsartan and Hydrochlorothiazide Tablets, Valsartan 160 MG and Hydrochlorothiazide 12.5 MG, 90 tablets per bottle, Rx Only, MFG: Arrow Pharm (Malta) LTD, Birzebbugia, BBG 3000 Malta. NDC: 54569-6480-0

Product Quantity:
524 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1110-2018

Code Information:
Expiry, lot: 4/30/2019: 8033130; 7/31/2019: 8068192, 8110183, 8080157, 8190195

Product Description:
Valsartan and Hydrochlorothiazide Tablets, Valsartan 320 MG and Hydrochlorothiazide 25 MG, 90 tablets per bottle, Rx Only, MFG: Arrow Pharm (Malta) LTD, Birzebbugia, BBG 3000 Malta. NDC: 54569-6488-0

Product Quantity:
531 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1111-2018

Code Information:
Expiry, lot: 1/31/2019: 7293219; 6/30/2019: 7362231, 8074161, 8110184, 8197215, 8114178, 8115123; 9/30/2018: 7132187, 7160161, 7180150, 7268239

Class II Drugs Event

Event ID:
80773

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/23/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs Limited Unit V
Unit V (SEZ Unit I in APIIC SEZ) Surv. No. 439-441, 458, Polepally Vill.
Jadcherla Mandal, Mahaboob Nagar India

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Camber Pharmaceuticals, Inc. Valsartan Tablets, USP, 40 mg, 30 Tablets Rx Only Manufactured for: Camber Pharmaceuticals, Inc. Piscataway NJ 08854 By: Hetero Hetero Labs Limited Unit V, Polepally Jadcherla Mahaboob Nagar - 509-301, India. NDC 31722-745-30 UPC 331722745307

Product Quantity:
316,380 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1113-2018

Code Information:
All Lots with expiration dates 7/2018 to 6/2020

Product Description:
Camber Pharmaceuticals, Inc. Valsartan Tablets, USP, 80 mg, 90 count bottles, Rx Only Manufactured for: Camber Pharmaceuticals, Inc. Piscataway NJ 08854 By: Hetero Hetero Labs Limited Unit V. Polepally Jadcherla Mahaboob Nagar - 509-301 India. NDC 31722-746-90 UPC 331722746908

Product Quantity:
394,896 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1114-2018

Code Information:
All Lots with expiration dates 7/2018 to 6/2020

Product Description:
Camber Pharmaceuticals, Inc. Valsartan Tablets, USP, 160 mg, 90 tablets Rx Only Manufactured for: Camber Pharmaceuticals, Inc. Piscataway NJ 08854 By: Hetero Hetero Labs Limited, Unit V, Pollepally Jadcherla Mahabubnagar - 509-301, India. NDC 31722-747-90 UPC 331722747905

Product Quantity:
441,408 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1115-2018

Code Information:
All Lots with expiration dates 7/2018 to 6/2020

Product Description:
Camber Pharmaceuticals, Inc. Valsartan Tablets, USP, 320 mg, 90 tablets, Rx Only Manufactured for: Camber Pharmaceuticals, Inc. Piscataway NJ 08854 By: Hetero Hetero Labs Limited Unit V, Pollepally Jadcherla Mahaboob Nagar - 509-301 India. NDC 31722-748-90 UPC 331722748902

Product Quantity:
441,408 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1116-2018

Code Information:
All Lots with expiration dates 7/2018 to 6/2020

Class II Drugs Event

Event ID:
80840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Products were distributed to one distributor in Alabama who may have further distributed the product to the consumer level.

Associated Products

Product Description:
Valsartan Tablets USP 320 mg, 90-count, plastic child resistant bottle, Rx Only, Preferred Pharmaceuticals, Inc., 1250 N. Lakeview Ave., Suite O, Anaheim, CA 92807, NDC 68788-6882-9

Product Quantity:
9 bottles consisting of 90 tables each bottle

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1107-2018

Code Information:
Lot # G2017F NDC 68788-6882-9

Class III Drugs Event

Event ID:
80802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
1718 Northrock Ct
Rockford IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Diltiazem HCl Extended-release Capsules, USP 120 mg, 80 capsules, 8 blister cards of 10 capsules each per carton, Rx Only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV. NDC 51079-947-08

Product Quantity:
408 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification results for related compound per the manufacturer

Recall Number:
D-1112-2018

Code Information:
Batch 3096049

Class III Drugs Event

Event ID:
80836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Product was distributed throughout the United States to wholesalers and retailers.

Associated Products

Product Description:
Valsartan Tablets USP, 40 mg, 30-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd Roorkee 0247661 India, Marketed by: Jubilant Cardista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-360-30

Product Quantity:
10,577 bottles

Reason for Recall:
Incorrect/Undeclared Excipient: There is a potential an incorrect grade of excipient was used during manufacturing.

Recall Number:
D-1103-2018

Code Information:
Lot #: VR117014A, VR117015A, Exp. 08/2019

Product Description:
Valsartan Tablets USP, 80 mg, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd Roorkee 0247661 India, Marketed by: Jubilant Cardista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-361-90

Product Quantity:
9,552 bottles

Reason for Recall:
Incorrect/Undeclared Excipient: There is a potential an incorrect grade of excipient was used during manufacturing.

Recall Number:
D-1104-2018

Code Information:
Lot #: VR217013A, Exp. 08/2019

Product Description:
Valsartan Tablets USP, 160 mg, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd Roorkee 0247661 India, Marketed by: Jubilant Cardista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-362-90

Product Quantity:
18,947 bottles

Reason for Recall:
Incorrect/Undeclared Excipient: There is a potential an incorrect grade of excipient was used during manufacturing.

Recall Number:
D-1105-2018

Code Information:
Lot #: VR317040A, VR317041A, VR317042A, VR317043A, Exp. 08/2019

Product Description:
Valsartan Tablets USP, 320 mg, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd Roorkee 0247661 India, Marketed by: Jubilant Cardista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-363-90

Product Quantity:
7,048 bottles

Reason for Recall:
Incorrect/Undeclared Excipient: There is a potential an incorrect grade of excipient was used during manufacturing.

Recall Number:
D-1106-2018

Code Information:
Lot #: VR417062A, Exp. 09/2019; VR417063A, VR417064A, Exp. 10/2019

Not Yet Classified Drugs Event

Event ID:
80719

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Westminster Pharmaceuticals Llc
1 & 2 154 Downing Street
Olive Branch MS United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Levothyroxine and Liothyronine (Thyroid Tablets, USP), 1 grain (60 mg), 100-count bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC, 154 Downing Street, Unit 1 & 2, Olive Branch, MS 38654, NDC 69367-156-04.

Product Quantity:
Unknown

Reason for Recall:
Failed Content Uniformity Specifications: Product was manufactured using an adulterated active pharmaceutical ingredient; additionally, lack of process controls and good manufacturing practices resulted in finished product failing content uniformity specifications which can result in a product having a strength that is more or less than is labeled.

Recall Number:

Code Information:
Lot #: 15617VP03, 15617VP01, 15617VP-02, Exp 7/31/2019; 15617VP06, 15617VP05, Exp 11/30/2019; 15617VP04, 15618004, 15618002, Exp 12/31/2019; 15618009, 15618008, Exp 2/29/2020; 15618011, Exp 3/31/2020.

Product Description:
Levothyroxine and Liothyronine (Thyroid Tablets, USP), 1 & 1/2 grain (90 mg), 100-count bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC, 154 Downing Street, Unit 1 & 2, Olive Branch, MS 38654, NDC 69367-157-04.

Product Quantity:
Unknown

Reason for Recall:
Failed Content Uniformity Specifications: Product was manufactured using an adulterated active pharmaceutical ingredient; additionally, lack of process controls and good manufacturing practices resulted in finished product failing content uniformity specifications which can result in a product having a strength that is more or less than is labeled.

Recall Number:

Code Information:
Lot #: 15717VP-01, 15717VP-02, 15717VP-03, Exp 7/31/2019; 15717002, Exp 12/31/2019; 15718004, Exp 3/31/2020.

Product Description:
Levothyroxine and Liothyronine (Thyroid Tablets, USP), 1/2 grain (30 mg), 100-count bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC, 154 Downing Street, Unit 1 & 2, Olive Branch, MS 38654, NDC 69367-155-04.

Product Quantity:
Unknown

Reason for Recall:
Failed Content Uniformity Specifications: Product was manufactured using an adulterated active pharmaceutical ingredient; additionally, lack of process controls and good manufacturing practices resulted in finished product failing content uniformity specifications which can result in a product having a strength that is more or less than is labeled.

Recall Number:

Code Information:
Lot #: 15517VP01, 15517VP02, 15517VP03, Exp 8/31/2019; 15518001, Exp 12/31/2019; 15518002, Exp 3/31/2020.

Product Description:
Levothyroxine and Liothyronine (Thyroid Tablets, USP), 1/4 grain (15 mg), 100-count bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC, 154 Downing Street, Unit 1 & 2, Olive Branch, MS 38654, NDC 69367-159-04.

Product Quantity:
Unknown

Reason for Recall:
Failed Content Uniformity Specifications: Product was manufactured using an adulterated active pharmaceutical ingredient; additionally, lack of process controls and good manufacturing practices resulted in finished product failing content uniformity specifications which can result in a product having a strength that is more or less than is labeled.

Recall Number:

Code Information:
Lot #: 15917VP03, 15917VP02, 15917VP01, Exp 10/31/2019; 15918004, 15918003, 15918002, 15918001, Exp 12/31/2019; 15918VP03, 15918VP02, 15918VP01, 15918005, Exp 2/29/2020; 15918007, 15918006, Exp 3/31/2020.

Product Description:
Levothyroxine and Liothyronine (Thyroid Tablets, USP), 2 grain (120 mg), 100-count bottles, Rx Only, Manufactured for: Westminster Pharmac

euticals, LLC, 154 Downing Street, Unit 1 & 2, Olive Branch, MS 38654, NDC 69367-158-04.

Product Quantity:
Unknown

Reason for Recall:
Failed Content Uniformity Specifications: Product was manufactured using an adulterated active pharmaceutical ingredient; additionally, lack of process controls and good manufacturing practices resulted in finished product failing content uniformity specifications which can result in a product having a strength that is more or less than is labeled.

Recall Number:

Code Information:
Lot #: 15817VP-01, 15817VP-02, 15817VP-03, Exp 9/30/2019; 15818001, Exp 3/31/2020.