Enforcement Report - Week of August 8, 2018

Class II Drugs Event

Event ID:
80364

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/02/2018

Initial Firm Notification of Consignee or Public:

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus OH United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg*. 50-count bottle, Rx only. Manufactured by: West-Ward Pharmaceuticals Corp. Eatontown, NJ 07724. NDC# 0143-2112-50.

Product Quantity:
29,048 bottles (1,452,400 tablets)

Reason for Recall:
Failed Dissolution Specifications:

Recall Number:
D-1024-2018

Code Information:
Lot# 71545B, Expiry date: 01/19

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg*. 500-count bottle, Rx only. Manufactured by: West-Ward Pharmaceuticals Corp. Eatontown, NJ 07724. NDC# 0143-2112-05.

Product Quantity:
29048 500-count bottles (14,524,000 tablets)

Reason for Recall:
Failed Dissolution Specifications:

Recall Number:
D-1025-2018

Code Information:
Lot# 71545A, Expiry date: 07/19

Class II Drugs Event

Event ID:
80399

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/28/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/02/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
PFIZER
275 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Daptomycin for Injection, 500 mg per vial, packaged as 1 Single-dose vial per carton, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-0106-01.

Product Quantity:
234,680 vials

Reason for Recall:
Microbial Contamination of Sterile Products: Product associated with reports of adverse events indicative of infusion reactions related to microbiological contamination.

Recall Number:
D-1023-2018

Code Information:
Lot #: 712453A, Exp 1-Nov-18; 771803A, Exp 1-May-19; 792103A, Exp 1-Jul-19; 800903A, Exp 1-Aug-19; 810853A, Exp 1-Sep-19; 841703A, 841753A, Exp 1-Dec-19; 850553A, Exp 1-Jan-20.

Class II Drugs Event

Event ID:
80553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VENSUN PHARMACEUTICALS INC
790 Township Line Rd
Yardley PA United States

Distribution Pattern:
Within the United States and Puerto Rico.

Associated Products

Product Description:
Potassium Citrate Extended-Release Tablets, USP, 15 mEq, 100-count bottles, Rx only, Manufactured for: Vensun Pharmaceuticals, Inc. Yardley, PA 19067, Manufactured by: Strides Shasun Limited, Puducherry - 605 014, India, NDC 42543-408-01.

Product Quantity:
11,652 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Tablet breakage

Recall Number:
D-1017-2018

Code Information:
Lot #: 9570024, Exp. Jun-2019; 9570027, 9570029, Exp. Jul-2019; 7702088A, 7702089A, Exp. Aug-2019.

Product Description:
Potassium Citrate Extended-Release Tablets, USP, 10 mEq, 100-count bottles, Rx only, Manufactured for: Vensun Pharmaceuticals, Inc. Yardley, PA 19067, Manufactured by: Strides Shasun Limited, Puducherry - 605 014, India, NDC 42543-407-01.

Product Quantity:
3,683 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Tablet breakage

Recall Number:
D-1018-2018

Code Information:
Lot #: 9570012, Exp. June-2019

Class II Drugs Event

Event ID:
80589

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs, Ltd. - Unit III
Plot 22-110, Part Ii, Ida Rangareddy, Jeedimetla
Hyderabad India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Indomethacin Capsules, USP, 50 mg, 100-count bottles, Rx only, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854; By: Hetero, Hetero Labs Limited, Jeedimetla, Hyderabad - 500 055, India; NDC 31722-543-01.

Product Quantity:
18,288 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: customer complaints of deformed, clumped, misshaped, melted or stuck together capsules.

Recall Number:
D-1019-2018

Code Information:
Lot #: E180315, Exp 12/19

Class II Drugs Event

Event ID:
80634

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/27/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bryant Ranch Prepack Inc.
1919 N Victory Pl
Burbank CA United States

Distribution Pattern:
Product was distributed in HI, IN, and FL.

Associated Products

Product Description:
Valsartan 80 mg tablets, 90-count bottles (NDC 63629-6922-2), 60-count bottles (63629-6922-3), 28-count bottles (63629-6922-4), Rx Only, Packaged by Bryant Ranch, Burbank, CA 91504.

Product Quantity:
690 tablets

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

Recall Number:
D-1027-2018

Code Information:
Lot # 111158; Exp. 02/19

Product Description:
Valsartan 320 mg tablets, 30-count bottles (NDC 63629-6905-1), 90-count bottles (NDC 63629-6905-2), 28-count bottles (NDC 6362-96905-3), Rx Only, Packaged by Bryant Ranch, Burbank, CA 91504.

Product Quantity:
990 tablets

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

Recall Number:
D-1028-2018

Code Information:
Lot # 114319; Exp. 10/18 Lot # 109004; Exp. 12/18

Product Description:
Valsartan 320 mg tablets, 90-count bottles (NDC 71335-0567-2), Rx Only, Packaged by Bryant Ranch, Burbank, CA 91504.

Product Quantity:
90 tablets

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

Recall Number:
D-1029-2018

Code Information:
Lot # 120879; Exp 10/19

Class II Drugs Event

Event ID:
80646

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/31/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to 3 medical facilities in Florida.

Associated Products

Product Description:
Valsartan/HCTZ 160 mg/12.5 mg tablet, 90-count bottle, Rx only, RemedyRepack, 625 Kolter Drive, Suite 4, Indiana, PA 15701

Product Quantity:
4 HDPE 90-count bottles (360 tablets)

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

Recall Number:
D-1020-2018

Code Information:
Lot # B0318652-070617; Exp. 07/18

Product Description:
Valsartan/HCTZ 320mg/12.5 mg tablet, 90-count bottle, Rx only, RemedyRepack, 625 Kolter Drive, Suite 4, Indiana, PA 15701

Product Quantity:
3 HDPE 90-count bottles (270 tablets)

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

Recall Number:
D-1021-2018

Code Information:
Lot # B0383153-122917; Exp. 12/18

Class II Drugs Event

Event ID:
80659

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MAJOR PHARMACEUTICALS
17177 N Laurel Park Dr
Livonia MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg, Rx Only, 30 tablets, 3 x 10 unit dose Cartons, Mfd. by: West-Ward Pharmaceuticals Corp., Eatontown, NY 07724; Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 USA. NDC: 0904-0430-04

Product Quantity:
3,161 Cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1026-2018

Code Information:
Lot: 71545AA, exp 7/2019

Class II Drugs Event

Event ID:
80674

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/01/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
H J Harkins Company Inc dba Pharma Pac
1400 W Grand Ave Ste F
Grover Beach CA United States

Distribution Pattern:
Product was distributed to a physician's office.

Associated Products

Product Description:
Valsartan tablets 160 mg, 90-count bottle, Rx Only, Repackaged by H.J. Harkins Co, Inc. Grover Beach, CA 93433, NDC 43547-0369-09. Tablet is yellow, capsule-shaped, biconvex, film-coated tablets debossed with 343 on one side and HH on the other side.

Product Quantity:
540 tablets

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

Recall Number:
D-1022-2018

Code Information:
Lot # VSA000OV Manufacturer's original lot # 343B17015, exp date 02/19 NDC 43547-0369-09

Class III Drugs Event

Event ID:
80442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Renaissance Lakewood, LLC
1200 Paco Way
Lakewood NJ United States

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
Fluconazole Injection, USP, Iso-Osmotic Sodium Chloride Diluent, 400 mg in 200 mL (2 mg/mL), 200 mL Single Dose Flexible Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India; NDC 36000-003-06.

Product Quantity:
3000 bags

Reason for Recall:
Superpotent Drug and Failed Stability Specifications: lot out of specification for elevated sodium chloride and elevated water vapor.

Recall Number:
D-1031-2018

Code Information:
Lot # A061213, Exp 09/18

Product Description:
Fluconazole Injection, USP, Iso-Osmotic Sodium Chloride Diluent, 200 mg in 100 mL (2 mg/mL), 100 mL Single Dose Flexible Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-002-10.

Product Quantity:
3664 bags

Reason for Recall:
Failed Stability Specifications: lot out of specification for elevated water vapor.

Recall Number:
D-1032-2018

Code Information:
Lot #: A0A0156, Exp 02/19

Product Description:
Fluconazole Injection, USP, Iso-Osmotic Sodium Chloride Diluent, 200 mg in 100 mL (2 mg/mL), 100 mL Single Dose Flexible Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC a) 36000-002-10 and b) 36000-002-06.

Product Quantity:
12088 bags

Reason for Recall:
Superpotent Drug: lots out of specification for elevated sodium chloride and fluconazole assay.

Recall Number:
D-1033-2018

Code Information:
Lot #: a) A060966, A060967, A060965, A061023, Exp 07/18; b) A060962, Exp 02/19

Not Yet Classified Drugs Event

Event ID:
80668

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:
Moxifloxacin Ophthalmic Solution USP, 0.5%, 5 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775, INDIA, NDC 68180-442-01

Product Quantity:
13,896 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: An out-of-specification result in the related substance test during three month long-term stability study.

Recall Number:

Code Information:
Lot #: H800393, Exp. 01/2020