Enforcement Report - Week of February 6, 2019

Class II Drugs Event

Event ID:
81193

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Gentamicin Sulfate Ophthalmic Solution, USP 0.3%, 5 mL dropper bottle, Rx Only, Manufactured by: Akorn, Inc. Lake Forest, IL 60045, NDC 17478-283-10

Product Quantity:
149,159 5mL bottles

Reason for Recall:
Presence of Particulate Matter: Crystalline particles were noticed at the 24 month clarity testing.

Recall Number:
D-0414-2019

Code Information:
Lots: 6C02A Exp. 02/19; 5K42A Exp. 09/2018; 7D47A Exp. 03/2020

Class II Drugs Event

Event ID:
81343

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/28/2019

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:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
GENTAMICIN OPTH-SOL 5ml Compare: Garamycin. 5-mL plastic dropper bottle, Mfg: AKORN 17478-0283-10. NDC 52959-0103-00

Product Quantity:
84, 5 ml bottles

Reason for Recall:
Presence of Particulate Matter: Crystalline particles were noticed by manufacturer at the 24 month clarity testing.

Recall Number:
D-0415-2019

Code Information:
Lot # GNT01AK, Exp. 02/19 & GNT07AK, Exp. 3/20

Class II Drugs Event

Event ID:
81811

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/28/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Duren Health Mart Pharmacy
215 Dexter L Woods Memorial Blvd
Waynesboro TN United States

Distribution Pattern:
TN only

Associated Products

Product Description:
Omeprazole 4 mg/mL Suspension, 150cc to 300 cc per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00000-0001-07

Product Quantity:
2700 cc

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0416-2019

Code Information:
N/A

Product Description:
Progesterone 10% cream, 12gm to 30gm per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00000-0002-99

Product Quantity:
200 grams

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0417-2019

Code Information:
N/A

Product Description:
Testosterone 0.1% cream, 30 grams, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00000-0000-98

Product Quantity:
300 grams

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0418-2019

Code Information:
N/A

Product Description:
Promethazine Gel 50 mg/mL, 1cc to 10cc per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00002-1901-03

Product Quantity:
876 cc

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0419-2019

Code Information:
N/A

Product Description:
Progesterone 100 mg SR capsules, 30-180 capsules per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN38485, NDC 00311-2003-01

Product Quantity:
1306 capsules

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0420-2019

Code Information:
N/A

Product Description:
Domperidone 10 mg capsules, 100-count per prescription, Rx only, Duren's Health Mart Pharmacy 215 Dexter Woods Blvd. Waynesboro, TN 38485, NDC 00507-2011-00

Product Quantity:
840 capsules

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0421-2019

Code Information:
N/A

Class II Drugs Event

Event ID:
81908

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/09/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/31/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

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

Distribution Pattern:
Product was distributed to 5 wholesalers, 2 drug chains and 1 supermarket who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Cephalexin for Oral Suspension USP 250mg/5 mL, Rx Only Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland, Manufactured by: Lupin Limited Mandideep 462 046 India --- NDC 68180-441-01

Product Quantity:
14,400 bottles

Reason for Recall:
CGMP Deviations; presence of extraneous material in the was observed in area that is between the primary package that is heat sealed and secondary packaging (poly-woven bag) of sucrose (an excipient) used in the finished product.

Recall Number:
D-0423-2019

Code Information:
lot F801282, Expiry June 2020

Class II Drugs Event

Event ID:
81910

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/27/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Prinston Pharmaceutical Inc
700 Atrium Dr
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Irbesartan Tablets 300 mg 90 count Rx only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Xunqiao, Linhai, Zhejiang 317024 China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 NDC 43547-376-09

Product Quantity:
19800 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0409-2019

Code Information:
331B18009

Product Description:
Irbesartan and HydrochlorothiazideTablets, USP 150/12.5 mg Rx Only 90 count Manufactured by: Zhejiang Huahai Pharmaceutical Co., Xunqiao, Linhai, Zhejiang 317024 China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 NDC 43547-330-09

Product Quantity:
2177 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0410-2019

Code Information:
325B18004

Product Description:
Irbesartan and Hydrochlorothiazide Tablets, USP 300/12.5 mg Rx Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xunqiao, Linhai, Zheijang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 30 count - NDC 43547-331-03

Product Quantity:
32692 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0411-2019

Code Information:
327A18001 327A18002

Product Description:
Irbesartan and Hydrochlorothiazide Tablets, USP 300/12.5 mg Rx Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xunqiao, Linhai, Zheijang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 90 count NDC 43547-331-09

Product Quantity:
12294 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0412-2019

Code Information:
327B18008 327B18009

Product Description:
Irbesartan and Hydrochlorothiazide Tablets, USP 150/12.5 mg Rx 30 Tablets Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xunqiao, Linhai, Zheijang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 NDC 43547-330-03

Product Quantity:
87505 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0413-2019

Code Information:
325D18004 325D18005

Class II Drugs Event

Event ID:
81930

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/04/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fexofenadine HCl Tablets, USP, 180 mg, packaged in a) 30-count bottles (NDC 0378-0782-93) and b) 500-count bottles (NDC 0378-0782-05); Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA.

Product Quantity:
88,090 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Related compound results obtained during routine stability testing was slightly elevated above specification.

Recall Number:
D-0428-2019

Code Information:
Lot #: a) 3085490, 3085491, Exp 04/19; b) 3085492, 3085493, 3085494, 3085495, 3085496, Exp 04/19

Class II Drugs Event

Event ID:
81958

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/30/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
BromSite (bromfenac ophthalmic solution) 0.075%, 5 mL bottles, Rx Only, Distributed by : Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 49708-754-41

Product Quantity:
69840 bottles

Reason for Recall:
Bromfenac Ophthalmic Solution, 0.075% (Sterile 5 mL) may have a lack of sterility assurance.

Recall Number:
D-0422-2019

Code Information:
Lot #: V18E01, Exp. 05/2020