Enforcement Report - Week of August 1, 2018

Class II Drugs Event

Event ID:
80485

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/12/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/24/2018

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:
Testosterone Cypionate Injection, USP, 200 mg/mL, Rx only, 10 mL vials, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries, Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-016-40

Product Quantity:
5215 units

Reason for Recall:
Presence of Particulate Matter: organic and inorganic compounds detected in vials of product.

Recall Number:
D-0977-2018

Code Information:
Lot #: JKS0280A, Exp. 06/2019

Class II Drugs Event

Event ID:
80525

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Prinston Pharmaceutical Inc
2002 Eastpark Blvd
Cranbury NJ United States

Distribution Pattern:
United States

Associated Products

Product Description:
Solco Healthcare US Valsartan, USP, 40 MG Tablets, 30- count bottle, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-367-03

Product Quantity:

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

Recall Number:
D-0968-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan, USP, 80 MG Tablets, 90-count bottle, Rx Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-368-09

Product Quantity:

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

Recall Number:
D-0969-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan, USP, 160 MG Tablets, 90-count bottles, Rx Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-369-09

Product Quantity:

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

Recall Number:
D-0970-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan, USP, 320 MG Tablets, 90-count bottle,Rx Only Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-370-09

Product Quantity:

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

Recall Number:
D-0971-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan and Hydrochlorothiazide, USP, 80 MG/12.5 MG Tablets, 90-count bottles, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-311-09

Product Quantity:

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

Recall Number:
D-0972-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan and Hydrochlorothiazide, USP, 160 MG/12.5 MG Tablets, 90-count bottles, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-312-09

Product Quantity:

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

Recall Number:
D-0973-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan and Hydrochlorothiazide, USP, 160 MG/25 MG Tablets, 90-count bottle, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-313-09

Product Quantity:

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

Recall Number:
D-0974-2018

Code Information:
All lots within expiry

Product Description:
Solco Healthcare US Valsartan and Hydrochlorothiazide, USP, 320 MG/12.5 MG Tablets, 90-count bottle, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-314-09

Product Quantity:

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

Recall Number:
D-0975-2018

Code Information:
All lots within expiry.

Product Description:
Solco Healthcare US Valsartan and Hydrochlorothiazide, USP, 320 MG/25 MG Tablets, 90-count bottles, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd. Xynqiao, Linhai, Zhejiang 317024, China Distributed by: Solco Healthcare US, LLC Cranbury, NJ 08512 USA NDC 43547-315-09

Product Quantity:

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

Recall Number:
D-0976-2018

Code Information:
All lots within expiry.

Class II Drugs Event

Event ID:
80538

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/24/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Product was distributed throughout the United States, including Hawaii and Puerto Rico

Associated Products

Product Description:
Valsartan and Hydrochlorothiazide (HCTZ) Tablets, USP 80 mg/12.5 mg tablets, 90 count-count bottle, Rx Only, Manufactured by: Arrow Pharma (M alta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054, NDC 0591-2315-19.

Product Quantity:
56,603 bottles

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

Recall Number:
D-0981-2018

Code Information:
Lot # 1191191M, 1191192M, 1191193M, 1191194M, 1191195M, 1238466M, 1238467M, 1253261M 1256125M, 1277709M

Product Description:
Valsartan and Hydrochlorothiazide (HCTZ) Tablets, USP 160 mg/12.5 mg tablets, USP 90-count bottle, Rx Only, Rx Only, Manufactured by: Arrow P harma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054. NDC 0591-2316-19.

Product Quantity:
195,234 bottles

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

Recall Number:
D-0982-2018

Code Information:
Lot Numbers: 1191160M, 1191161M, 1191162A, 1219363M, 1219364M, 1219365A, 1225613A, 1233944M, 1233945M, 1253253M, 1253254M

Product Description:
Valsartan and Hydrochlorothiazide (HCTZ) Tablets, USP 160 mg/25 mg tablets, USP 90-count bottle, Rx Only, Rx Only, Manufactured by: Arrow Ph arma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054. NDC 0591-2317-19.

Product Quantity:
99,554 bottles

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

Recall Number:
D-0983-2018

Code Information:
Lot Numbers: 1191164M, 1191165M, 1191166M, 1191167A, 1225612M, 1250717M, 1256111M, 1288798M

Product Description:
Valsartan and Hydrochlorothiazide (HCTZ) Tablets, USP 320 mg/12.5 mg tablets, USP, 90-count bottle, Rx Only, Rx Only, Manufactured by: Arrow P harma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054. NDC 0591-2318-19

Product Quantity:
64,168 bottles

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

Recall Number:
D-0984-2018

Code Information:
Lot Numbers: 1191185M, 1191186M, 1225615M, 1233948M, 1250718M, 1253257M

Product Description:
Valsartan and Hydrochlorothiazide (HCTZ) Tablets, USP 320 mg/25 mg tablets, USP, 90-count bottle, Rx Only, Rx Only, Manufactured by: Arrow Pharma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054. NDC 0591-2318-19.

Product Quantity:
164,922 bottles

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

Recall Number:
D-0985-2018

Code Information:
Lot Numbers: 1191188M, 1191189M, 1191190M, 1199220M, 1217576M, 1217577M, 1217578M, 1220832M, 1220833M, 1247283M, 1247284M, 1247285M, 1247286M, 1247287A, 1280632M, 1280633M

Product Description:
Valsartan Tablets, USP 40 mg, 30-count bottle (NDC 0591-2167-30), 90-count bottle (NDC 0591-2167-19), Rx Only, Rx Only, Manufactured by: Arrow Pharma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054

Product Quantity:
8,046 30-count bottles, 20,841 90-count bottles

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

Recall Number:
D-0986-2018

Code Information:
Lot Numbers: NDC 0591-2167-30 1196936A, 1238463A, 1270617A NDC 0591-2167-19 1196934M, 1238462M, 1268429A

Product Description:
Valsartan Tablets, USP 80 mg, 90-count bottle (NDC 0591-2168-19), 1000-count bottle (NDC 0591-2168-10), Rx Only, Rx Only, Manufactured by: Arrow Pharma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054

Product Quantity:
30,793 90-count bottles, 1,158 1000-count bottles

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

Recall Number:
D-0987-2018

Code Information:
Lot Numbers: NDC 0591-2168-19 1175947M, 1175948M, 1177115A, 1219361A, 1240434M, 1250704M NDC 0591-2168-10 1177114A, 1219360M, 1250706A

Product Description:
Valsartan Tablets, USP 160 mg, 90-count bottle (NDC 0591-2169-19), 1000-count bottle (NDC 0591-2169-10), Rx Only, Rx Only, Manufactured by: Arrow Pharma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054

Product Quantity:
15,347 90-count bottles, 8,378 1000-count bottles

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

Recall Number:
D-0988-2018

Code Information:
NDC 0591-2169-19 Lot Numbers: 1177880A, 1220831A, 1263941A NDC 0591-2169-10 1175922M, 1220826M, 1236294M, 1240427M, 1270616A

Product Description:
Valsartan Tablets, USP 320 mg, 90-count bottle (NDC 0591-2170-19), 500-count bottle (NDC 0591-2170-05), Rx Only, Rx Only, Manufactured by: A rrow Pharma (Malta) Ltd. India, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054.

Product Quantity:
13,555 90-count bottles; 2,892 500-count bottles

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

Recall Number:
D-0989-2018

Code Information:
NDC 0591-2170-19 Lot Numbers: 1208002A, 1247282M, 1263944M NDC 0591-2170-05 Lot Numbers: 1208000M, 1208001M, 1240425A

Class II Drugs Event

Event ID:
80557

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2018

Voluntary / Mandated:
Voluntary: FDA Requested

Center Classification Date:
07/20/2018

Initial Firm Notification of Consignee or Public:

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

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Unit Dose Valsartan Tablets, USP, 80 mg. Rx only, Distributed by: Major Pharmaceuticals, Livonia, MI 48152, NDC# 0904-6594-61.

Product Quantity:
5,464 cartons

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

Recall Number:
D-0966-2018

Code Information:
Major Label Unit Dose 10 x 10 Cartons 80 mg Item # 302086. Lot# T-01270 (Expiry: 7/18). Lot# T-01466 (Expiry: 7/18). Lot# T-01500 (Expiry:2/19). Lot# T-01596 (Expiry: 2/19). Lot# T-01625 (Expiry: 2/19). Lot# T-01712 (Expiry: 2/19). Lot# T-01795 (5/19). Lot# T-01807 (Expiry: 5/19).

Product Description:
Unit Dose Valsartan Tablets, USP. 160 mg. Rx only.,Distributed by: Major Pharmaceuticals, Livonia, MI 48152, NDC# 0904-6594-61. NDC# 0904-65 95-61.

Product Quantity:
4,556 cartons

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

Recall Number:
D-0967-2018

Code Information:
Major Label Unit Dose 10 x 10 Cartons 160 mg Item # 302087. Lot# T-01269 (Expiry: 7/18). Lot# T-01524 (Expiry: 2/19). Lot# T-01646 (Expiry: 5/19). Lot# T-01668 (Expiry: 5/19). Lot# T-01788 (Expiry: 5/19).

Class III Drugs Event

Event ID:
80397

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/27/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/25/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aidarex Pharmaceuticals LLC
595 N Smith Ave
Corona CA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Enalapril Maleate, USP 2.5MG, 90-count bottle, RX only. Packaged By: Aidarex Pharmaceuticals. Mfg: Wockhardt Ltd. India. NDC: 33261-0977-90

Product Quantity:
11, 90-count bottles

Reason for Recall:
Out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.

Recall Number:
D-0990-2018

Code Information:
Lots: 56698-1, EXP 1/31/2019; 56698-2, EXP 4/30/2019

Product Description:
Enalapril Maleate, USP 5MG, 90-count bottle, RX only. Packaged By: Aidarex Pharmaceuticals. Mfg: Wockhardt Ltd. India. NDC: 33261-0693-90

Product Quantity:
61, 90-count bottles

Reason for Recall:
Out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.

Recall Number:
D-0991-2018

Code Information:
Lots: 51904-1, EXP: 01/31/2018; 51904-4, 52885-1, EXP: 03/31/2018; 52885-3, EXP: 04/30/2018; 52885-4,EXP: 05/28/2018; 53840-2,EXP: 5/28/2018; 53840-3, EXP:6/30/2018; 53840-4, EXP:8/31/2018; 56665-1, EXP: 01/31/2019; 58596-1, EXP: 05/28/2019.

Product Description:
Enalapril Maleate, USP 5MG, 30-count bottle, RX only. Packaged By: Aidarex Pharmaceuticals. Mfg: Wockhardt Ltd. India. NDC: 33261-0693-30

Product Quantity:
25, 30-count bottles

Reason for Recall:
Out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.

Recall Number:
D-0992-2018

Code Information:
Lots: 51904-2, EXP: 01/31/2018; 51904-3, EXP: 02/28/2018; 51904-5, EXP: 03/31/2018; 52885-2, EXP: 03/31/2018, 53840-1, EXP: 5/28/2018.

Class III Drugs Event

Event ID:
80463

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/24/2018

Initial Firm Notification of Consignee or Public:

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Enalapril Maleate Tablets, USP, 2.5 mg, 100 Tablets (10 x 10) Unit Dose per carton, Rx only, Manufactured by: Wockhardt Limited, H-14/2, M.I.D.C. Area, Waluj, Aurangabad, Maharashtra, India; Distributed by: Wockhardt USA LLC., 20 Waterview Blvd., Parsippany, NJ 07054; Distributed by: MAJOR Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152; NDC 0904-5609-61.

Product Quantity:
3,397 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Sub-recall because this repackaged product was recalled by the manufacturing firm, Wockhardt, due to out-of-specification results for the Enalapril DiKetopiperazine degradation product.

Recall Number:
D-0979-2018

Code Information:
Lot #: T-01083, Exp 08/18; DR10447A, Exp 09/18; DS10201A, Exp 07/19; DS10201B, DS10201C, Exp 08/19; DS10319A, Exp 10/19.

Product Description:
Enalapril Maleate Tablets, USP, 5 mg, 100 Tablets (10 x 10) Unit Dose per carton, Rx only, Manufactured by: Wockhardt Limited, H-14/2, M.I.D.C. Area, Waluj, Aurangabad, Maharashtra, India; Distributed by: Wockhardt USA LLC., 20 Waterview Blvd., Parsippany, NJ 07054; Distributed by: MAJOR Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152; NDC 0904-5502-61.

Product Quantity:
5,933 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Sub-recall because this repackaged product was recalled by the manufacturing firm, Wockhardt, due to out-of-specification results for the Enalapril DiKetopiperazine degradation product.

Recall Number:
D-0980-2018

Code Information:
Lot #: T-01082, Exp 08/18; DR10445A, Exp 09/18; DR10443A, Exp 12/18; DR10445B, Exp 03/19; DR10725A, Exp 07/19; DS10024A, DS10040A, Exp 10/19.