Enforcement Report - Week of November 28, 2018

Class II Drugs Event

Event ID:
81458

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/20/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Sciegen Pharmaceuticals Inc
89 Arkay Dr
Hauppauge NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Westminister Irbesartan Tablets, USP, 75 mg (a) 30-count bottle (NDC 69367-119-01), (b) 90-count bottle (NDC 69367-119-03), Rx Only, Manufactured by ScieGen Pharmaceuticals Inc Hauppauge, NY 11755 Manufactured for Westminister Pharmaceuticals LLC Olive Branch, MS 20854 Made in the USA

Product Quantity:
2,977 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0267-2019

Code Information:
69367-119-01 Irbesartan 75mg Tablets, 30 count bottle B160002A Sep-19 69367-119-03 Irbesartan 75mg Tablets, 90 count bottle B160002B Sep-19

Product Description:
Westminister Irbesartan Tablets, USP, 150 mg, (a) 30-count bottle (NDC 69367-120-01), (b) 90-count bottle (NDC 69367-120-03), Rx Only, Manufactured by ScieGen Pharmaceuticals Inc. Hauppauge, NY 11755, Manufactured for Westminster Pharmaceuticals LLC Olive Branch, MS 20854, Made in the USA.

Product Quantity:
5,061 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0268-2019

Code Information:
69367-120-01 Irbesartan 150mg Tablets, 30 count bottle B161005A Sep-19 C161002A Feb-20 69367-120-03 Irbesartan 150mg Tablets, 90 count bottle B161005B Sep-19 C161002B Feb-20

Product Description:
Westminister Irbesartan Tablets, USP, 300mg, Rx Only,(a) 30-count bottle (NDC 69367-121-01, (b) 90-count bottle (NDC 69367-121-03), Manufactured by ScieGen Pharmaceuticals Inc. Hauppauge, NY 11755. Manufactured for Westminster Pharmaceuticals LLC Olive Branch, MS 20854 Made in the USA.

Product Quantity:
5,989 HDPE

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0269-2019

Code Information:
69367-121-01 Irbesartan 300mg Tablets, 30 count bottle B162008A Sep-19 C162002A Feb-20 69367-121-03 Irbesartan 300mg Tablets, 90 count bottle B162008B Sep-19 C162002B Feb-20

Product Description:
GSMS Irbesartan Tablets, USP, 75 mg, 30-count bottle, Rx Only, Manufactured by ScieGen Pharmaceuticals, Inc. Hauppauge, NY 11788 Marketed by: GSMS Incorporated Camarillo, CA 93012 USA, NDC 60429-640-90.

Product Quantity:
3,835 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0270-2019

Code Information:
60429-640-90 Irbesartan 75mg Tablets, 90 Count Bottle B160003 Sep-19 B160004 Sep-19

Product Description:
GSMS Irbesartan Tablets, USP, 150 mg, (a) 30-count bottle (NDC 60429-641-30), (b) 90-count bottle (NDC 60429-641-90), Rx Only, Manufactured by ScieGen Pharmaceuticals, Inc. Hauppauge, NY 11788, Marketed by: GSMS Incorporated Camarillo, CA 93012 USA.

Product Quantity:
18,760 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0271-2019

Code Information:
60429-641-90 Irbesartan 150mg Tablets, 90 Count Bottle B161003 Sep-19 B161004 Sep-19 B161006 Sep-19 B161007 Sep-19 B161008 Nov-19 B161009 Nov-19 B161010 Nov-19 C161001 Feb-20 C161003 May-20 60429-641-30 Irbesartan 150mg Tablets, 30 Count Bottle GS019526 Nov-19 GS020252 Nov-19 GS020958 Nov-19

Product Description:
GSMS Irbesartan Tablets, USP, 300 mg,(a) 30-count bottle (NDC 60429-642-30), (b) 90-count bottle (NDC 60429-642-90), Rx Only, Manufactured by ScieGen Pharmaceuticals, Inc. Hauppauge, NY 11788, Marketed by: GSMS Incorporated Camarillo, CA 93012 USA.

Product Quantity:
30,194 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodimethylamine (NDEA) in product.

Recall Number:
D-0272-2019

Code Information:
60429-642-30 Irbesartan 300mg Tablets, 30 Count Bottle GS019036 Sep-19 GS019073 Sep-19 GS021472 Nov-19 GS021530 Nov-19 GS022234 Feb-20 60429-642-90 Irbesartan 300mg Tablets, 90 Count Bottle B162009 Sep-19 B162010 Sep-19 B162011 Sep-19 B162012 Nov-19 B162013 Nov-19 B162014 Nov-19 B162015 Nov-19 C162001 Feb-20

Class II Drugs Event

Event ID:
81473

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/06/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Antacid Tablets, Calcium Carbonate chewable tablets, 750mg, 60-count bottle, OTC, [Healthy Accents brand NDC: 55316-014-72, Distributed by DZA Brands, LLC, Salisbury, NC 28147, Scarborough, ME 04074], [HealthMart Pharmacy brand NDC: 62011-0295-1, Distributed by McKessen, One Post Street, San Francisco, CA 94104], [DG health brand NDC: 55910-717-72, Distributed By Dolgencorp, LLC, 100 Mission Ridge, Goodlettsville, TN 37072]

Product Quantity:
70,170 bottles

Reason for Recall:
Presence of foreign substance: Product found to contain metal particles.

Recall Number:
D-0266-2019

Code Information:
Lots: PA17-412, PA17-077, PA17-196,PA17-127, PA17-150, Exp 11/18

Class II Drugs Event

Event ID:
81500

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
IRBESARTAN Tablets, USP 75 mg 90-count bottle, Rx Only, Manufactured by: SciGen Pharmaceuticals, Inc. Hauppauge, NY 11788, Distributed by: GSMS, Incorporated, Camarillo, CA 93012, USA, NDC 60429-640-90.

Product Quantity:
2,439 bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodiethylamine (NDEA) in product.

Recall Number:
D-0263-2019

Code Information:
Lot Numbers: B160003; Exp. 09/19 B160004; Exp. 09/19

Product Description:
IRBESARTAN Tablets, USP 150 mg (a) 30-count bottle (NDC 60429-641-30), (b) 90-count bottle (NDC 60429-641-90) Rx Only, Manufactured by: SciGen Pharmaceuticals, Inc. Hauppauge, NY 11788, Distributed by: GSMS, Incorporated, Camarillo, CA 93012, USA.

Product Quantity:
15,917 bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodiethylamine (NDEA) in product.

Recall Number:
D-0264-2019

Code Information:
Lot Numbers: 30-count bottles: GS019526; Exp. 11/19 GS020252; Exp. 11/19 GS020958; Exp. 11/19 Lot Numbers: 90-count bottles B161003; Exp. 09/19 B161004; Exp. 09/19 B161006; Exp. 09/19 B161007; Exp. 09/19 B161008; Exp. 11/19 B161009; Exp. 11/19 B161010; Exp. 11/19 C161001; Exp. 02/20 C161003; Exp. 05/20

Product Description:
IRBESARTAN Tablets, USP 300 mg (a) 30-count bottle (NDC 60429-642-30), (b) 90-count bottle (NDC 60429-642-90) Rx Only, Manufactured by: SciGen Pharmaceuticals, Inc. Hauppauge, NY 11788, Distributed by: GSMS, Incorporated, Camarillo, CA 93012, USA.

Product Quantity:
12,502 bottles

Reason for Recall:
CGMP Deviations: FDA laboratory testing confirmed presence of an impurity, N-nitrosodiethylamine (NDEA) in product.

Recall Number:
D-0265-2019

Code Information:
Lot Numbers: 30-count bottles GS019036; Exp 09/19 GS019073; Exp. 09/19 GS021472; Exp. 11/19 GS021530; Exp. 11/19 GS022234; Exp. 02/20 90-count bottles B162009; Exp. 09/19 B162010; Exp. 09/19 B162011; Exp. 09/19 B162012; Exp. 11/19 B162013; Exp. 11/19 B162014; Exp. 11/19 B162015; Exp. 11/19 C162001; Exp. 02/20

Class II Drugs Event

Event ID:
81510

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ecolab Inc
Level 7 370 N
Saint Paul MN United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Equi-Soft Foam, Antimicrobial Hand Soap, 0.55% Benzalkonium Chloride, 25 fl oz (750 mL), OTC, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102, NDC 47593-521-41

Product Quantity:
12,540 bottles

Reason for Recall:
Labeling: Label mix-up - the label on the product may not match the formula in the bottle.

Recall Number:
D-0274-2019

Code Information:
Lot# L062881, Exp 06/20, 5338HU1800, Exp 08/20

Product Description:
Medi-Stat Foam, Antimicrobial Hand Soap, Chloroxylenol 0.5%, 1250 mL (42.3 fl oz), OTC, Ecolab, 370 Wabasha Street N, St. Paul, MN 55102, NDC 47593-503-59

Product Quantity:
14,108 bottles

Reason for Recall:
Labeling: Label mix-up - the label on the product may not match the formula in the bottle.

Recall Number:
D-0275-2019

Code Information:
Lot#: L062281, Exp 06/20

Class II Drugs Event

Event ID:
81530

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
U.S.A.nationwide

Associated Products

Product Description:
Clopidogrel Tablets, USP, 300 mg, 30 (5 x 6 unit-dose) count blister pack, Rx only, Manufactured by Dr. Reddy's Laboratories Limited, Srikakulam - 532 409, India, NDC 55111-671-31

Product Quantity:
4,212 (30-count blister pack)

Reason for Recall:
Failed Dissolution Specification: Out-of-Specification results were observed for dissolution at 18th month stability testing.

Recall Number:
D-0283-2019

Code Information:
Lot #: T600530, Exp 11/18

Class III Drugs Event

Event ID:
81553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/20/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AMERICAN HEALTH PACKAGING
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Nitrofurantoin Capsules USP (Monohydrate/Macrocrystals), 100 mg, 100-count Unit Dose Blisters, Rx only, Amerisource Health Services DBA American Health Packaging, 2550-A John Glenn Avenue Columbus, OH 43217, NDC 68084-446-01 (Individual Dose NDC: 68064-446-11)

Product Quantity:
4508 blister packs

Reason for Recall:
Cross contamination with other products: This sub-recall is being initiated in support of the recall by the manufacturer (Sandoz) dated 11/1/18, which included lots that were repackaged by American Health Packaging. Sandoz stated that "These lots are being recalled due to the potential presence of unrelated ingredients (i.e. traces of active ingredients of Benazepril, Haloperidol and Perphenazine), which were identified through a manufacturing investigation."

Recall Number:
D-0273-2019

Code Information:
Lot#: 180310, 180612, Exp 03/31/20