Enforcement Report - Week of April 19, 2017

Class II Drugs Event

Event ID:
76714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/01/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/12/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Signature Club A Ltd
550 N Reo St Ste 300
Tampa FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Double Hyaluronic 1000, 'AN OUNCE OF GOLD' Volumizing Day Cream, Broad Spectrum SPF 30+, (Octinoxate 7.725%, Oxybenzone 6.18%, Octisalate 5.15%, Avobenzone 3.09%), Net Wt. 1.8 oz. (51 g) jar, Distributed by Signature Club A, Ltd, Tampa, FL 33609.

Product Quantity:
1,237 jars

Reason for Recall:
Microbial Contamination of Non-Sterile Products: odor complaint of product due to microbial contamination.

Recall Number:
D-0662-2017

Code Information:
Lot #: 1626253/1746. Exp 10/18

Class II Drugs Event

Event ID:
76732

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/11/2017

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

Associated Products

Product Description:
LATANOPROST OPHTHALMIC SOLUTION, 0.005%, 125 ug/2.5 mL, packaged in 2.5 mL bottle, Rx only, Manufactured for: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-625-12

Product Quantity:
107,940 bottles

Reason for Recall:
Lack of assurance of sterility: product was found to be empty, under-filled, or leaking.

Recall Number:
D-0661-2017

Code Information:
Lot # LAB15G52, LAB11G52, Exp 6/17; LAB18I52, Exp 8/17; LAB9L52, 11/17; LAB1A62, LAB9A62, Exp 12/17

Class II Drugs Event

Event ID:
76863

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/08/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/12/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Mckesson Medical Surgical
9954 Mayland Dr
Henrico VA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
hydrALAZINE HYDROCHLORIDE INJECTION, USP, 20 mg/mL, 1 mL Single Dose Vial, packaged in 25 Vials per carton, Rx only, APP Fresenius Kabi USA, LLC, Lake Surich, IL 60047, NDC 63323-614-01, Distributed by McKesson Medical-Surgical, Inc.

Product Quantity:
98 vials

Reason for Recall:
Temperature Abuse: Certain pieces of these lots distributed by McKesson Medical Surgical Inc. were inadvertently stored refrigerated rather than the labeled room temperature recommendation.

Recall Number:
D-0668-2017

Code Information:
Lot #s: 6114311, 6114717, Exp 05/18

Class II Drugs Event

Event ID:
76873

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/12/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medisca, Inc.
661 State Route 3 Unit C
Plattsburgh NY United States

Distribution Pattern:
Nationwide, Australia, Bahamas, Italy, Singapore, Thailand, United Kingdom

Associated Products

Product Description:
ESTRIOL, USP (Micronized) Bulk, in a) 5 grams (NDC 38779-0732-03), b) 25 grams (NDC 38779-0732-04) , c) 100 grams (NDC 38779-0732-05), and d) 1 Kg (NDC 38779-0732-09) bottles, Packed by MEDISCA, INC. PLATTSBURGH, NY 12901; Product Code 0732

Product Quantity:

Reason for Recall:
cGMP Deviations; manufacturer initiated recall of API product after deficiencies noted during a recent FDA inspection

Recall Number:
D-0663-2017

Code Information:
a) 126317/D,126317/F,127288/C, 127296/D, 136212/C, 137155/C,137156/C, 138638/C,138646/B, 138646/E, 138646/I b) 126317/C, 126317/E, 127288/B, 127296/C, 136212/B, 137155/B, 137156/B, 138638/B, 138646/A, 138646/D,138646/H c) 126317/B,127288/A,127296/B, 136212/A, 137155/A, 137156/A,138638/A, 138646/C, 138646/G, 141219/A d) 126317/A, 127296/A, 138646/F

Product Description:
ESTRONE, USP Bulk, in a) 100 mgs (NDC 38779-0891-05), b) 1 gram (NDC 38779-0891-06), c) 5 grams (NDC 38779-0891-03), d) 25 grams (NDC 38779-0891-04), and e) 100 grams (NDC 38779-0891-09) Bottles, Packed by MEDISCA INC. PLATTSBURGH, NY 12901; Product Code 0891

Product Quantity:

Reason for Recall:
cGMP Deviations; manufacturer initiated recall of API product after deficiencies noted during a recent FDA inspection

Recall Number:
D-0664-2017

Code Information:
a) 124880/D,124880/O, 130940/J, 135312/E b) 124880/C 124880/F 124880/I 124880/N 130940/D 130940/I 135312/D 135312/I 136546/D 139489/B c) 124880/B, 124880/H, 124880/M, 130940/C, 130940/H, 135312/C, 135312/H, 136546/C d) 124880/A ,130940/B, 130940/G, 135312/B, 135312/G, 136546/B, 139489/A e) 124880/G, 124880/J, 124880/L,130940/A, 130940/F, 135312/A, 135312/F, 136546/A

Product Description:
ESTRADIOL, USP (Hemihydrate)(Micronized), in a) 100 mg (NDC 38779-0869-07), b) 1 g (NDC 38779-0869-06), c) 5 g (NDC 38779-0869-03), d) 10 g (NDC 38779-0869-01), e) 25 g (NDC 38779-0869-04), f) 100 g (NDC 38779-0869-05) , g) 500 g (NDC 38779-0869-08), h) 1 Kg (NDC 38779-0869-09) bottles, Packed by MEDISCA INC. PLATTSBURGH, NY 12901; Product Code 0869

Product Quantity:

Reason for Recall:
cGMP Deviations; manufacturer initiated recall of API product after deficiencies noted during a recent FDA inspection

Recall Number:
D-0665-2017

Code Information:
a) 137169/F b) 129670/G, 129670/K, 130942/G, 130942/L, 131429/G, 131430/G, 137169/E c) 129670/F,129670/J, 130942/F, 130942/K 131429/F, 131430/F, 137169/D, d) 129670/E, 129670/I,130942/E, 130942/J,131429/E, 131430/E, 137169/C e) 129670/D, 129670/H, 130942/D, 130942/I, 131429/D, 131430/D, 131430/H, 137169/B f) 129670/C, 130942/C, 130942/H, 131429/C, 131430/C, 137169/A, 137169/F g) 129670/B, 130942/B, 131429/B, 131430/B h) 129670/A, 130942/A ,131429/A, 131430/A

Product Description:
ESTRADIOL, USP Bulk (Hemihydrate), in a) 25 g (NDC 38779-2261-04) and b) 100 g (NDC 38779-2261-05) bottles, Packed by MEDISCA INC. PLATTSBURGH, NY Product Code 2261

Product Quantity:

Reason for Recall:
cGMP Deviations; manufacturer initiated recall of API product after deficiencies noted during a recent FDA inspection

Recall Number:
D-0666-2017

Code Information:
a) 129669/C, 129669/F, 129669/H, 129669/J, 130941/B 130941/D, 130941/F, 136108/B, 139091/B; b) 129669/B, 129669/E, 130941/A, 130941/C, 130941/E,130941/G, 136108/A,

Class II Drugs Event

Event ID:
76890

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Qinhuangdao Zizhu Pharmaceutical, Co.
No 10, Longhai Road Economic & Technological Development Zon
Qinhuangdao China

Distribution Pattern:
Product distributed to NY, TX, SC, CO, MN and NJ

Associated Products

Product Description:
Estradiol Micronized Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd, Qinhuangdao 066004, China (NDC 44132-001-01) (44132-001-06)

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0654-2017

Code Information:
Batch 80001512002 to Batch 80801604003, exp 10/22/2017 through 3/30/3018

Product Description:
Estradiol Non-Micronized, USP, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd, Qinhuangdao 066004, China

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0655-2017

Code Information:
Batch 80701510001 to Batch 80001607002, exp 10/22/2017 through 7/5/2018

Product Description:
Estriol Micronized, USP, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd, Qinhuangdao 066004, China 44132-007-06

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0656-2017

Code Information:
Batch 81801504002 to 81801701003, exp 4/12/2017 through 1/19/2019

Product Description:
Estrone Micronized, USP, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd., Qinhuangdao 066004, China (NDC 44132-003-04) (NDC 44132-003-02)(NDC 44132-003-06)

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0657-2017

Code Information:
Batch 82801505001 to 82801606001, exp 5/4/2017 through 5/19/2018

Product Description:
Testosterone Micronized, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd., Qinhuangdao 066004, China (NDC 44132-006-06)

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0658-2017

Code Information:
Batch 78801507001 to 78901612003, exp 6/22/2017 through 11/21/2018

Product Description:
Ethinyl Estradiol Micronized, USP, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd, Qinhuangdao 066004, China (NDC 44132-002-05)

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0659-2017

Code Information:
Batch 73801506007 to 73801603001, exp 5/31/2017 through 1/15/2018

Product Description:
Levonorgestrel Non-Micronized, USP, Bulk, Rx only, For Prescription Compounding, Manufactured by Qinhuangdao Zizhu Pharmaceutical Co., Ltd., Qinhuangdao 066004, China (NDC 44132-012-01),

Product Quantity:

Reason for Recall:
cGMP Deviations; lack of quality assurance.

Recall Number:
D-0660-2017

Code Information:
Batch 70001602009, 2/21/2021

Class III Drugs Event

Event ID:
76231

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novel Laboratories, Inc.
390 & 400 Campus Drive
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Fluocinolone Acetonide Topical Solution USP 0.01% For Topical Use Only, Not for Ophthalmic Use, 60 mL bottle, Rx Only, Manufactured for Gavis Pharmaceuticals, LLC, Somerset NJ 08873, Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873, NDC 43386-069-60

Product Quantity:
7,656 bottles

Reason for Recall:
Chemical Contamination

Recall Number:
D-0653-2017

Code Information:
Lot # M15496; Exp. 10/17 Lot # M15507; Exp. 12/17

Class III Drugs Event

Event ID:
76738

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/07/2017

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

Recalling Firm:
Citron Pharma Llc
2 Tower Center Blvd Ste 1101
East Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Penicillin V Potassium Tablets, USP 500 mg (800,000 units) 1000 count bottles, Rx Only, Distributed by: Citron Pharma LLC, East Brunswick, NJ --- NDC 57237-041-99

Product Quantity:
420 bottles

Reason for Recall:
Presence of Foreign Tablet/Capsule; Amoxicillin 500 mg was found in bottles of Penicillin V potassium 500 mg

Recall Number:
D-0652-2017

Code Information:
Batch Numbers: PE5015069-A, exp 11/2018

Class III Drugs Event

Event ID:
76748

Product Type:
Drugs

Status:
Ongoing

Date Terminated: