Enforcement Report - Week of September 20, 2017

Class I Drugs Event

Event ID:
77664

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Andropharm, LLC
1140 Holland Dr Ste 12
Boca Raton FL United States

Distribution Pattern:
Florida

Associated Products

Product Description:
ANDROPHARM STEN Z (2, 17a-Dimethyl-17b-hydroxy-5a-androst-1-en-3-one 10mg and 17b-hydroxy-2a, 17b-dimethyl-5a-androstan-3-one azine 10 mg) capsule, packaged in 60-count bottle, Andropharm.com, UPC: 6 42125 50294 8

Product Quantity:
150 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: product label states it contains anabolic steroids.

Recall Number:
D-1142-2017

Code Information:
All lots remaining within expiry.

Product Description:
ANDROPHARM M1 ALPHA (Methyl-1-Etiocholenolol-Epietiocholanollone 20 mg) capsule, packaged in 60-count bottle, Amazon.com, UPC 6 42125 50292 4

Product Quantity:
1250 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: product label states it contains anabolic steroids.

Recall Number:
D-1143-2017

Code Information:
All lots remaining within expiry.

Class I Drugs Event

Event ID:
77768

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

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

Recalling Firm:
BESTHERBS COFFEE LLC
2420 E Arkansas Ln Ste 216
Arlington TX United States

Distribution Pattern:
Recalling firm only distributed to 2 consignees in TX; however recalling f irm reported that product is then distributed U.S. nationwide to consume rs via individuals or internet

Associated Products

Product Description:
New Kopi Jantan Tradisional Natural Herbs Coffee, packaged in 13 gram red packets, and each box contains 25 packets, Made in Malaysia, USA Distributor: Bestherbscoffee LLC (USA), Email: bestherbscoffee@yahoo.com

Product Quantity:
6,250 packets

Reason for Recall:
Marketed without an approved NDA/ANDA: presence of undeclared desmethyl carbodenafil and undeclared milk.

Recall Number:
D-1144-2017

Code Information:
UPC 557205060083 ,Exp 5/24/18

Class I Drugs Event

Event ID:
77812

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/21/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Chiavna Saffron LLC
14235 Boren St Apt 201
Huntersville NC United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Super Panther 7K Capsules 1250 mg blend, a) 1 count blister cards shipped in boxes of 30 (UPC# 6015577513247); and b) 6 count bottles (UPC# 601577513209), Distributed by SX Power CO., Brooklyn, NY

Product Quantity:
211 bottles; 339 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA;FDA analysis found product to be tainted with sildendafil and tadalafil

Recall Number:
D-1145-2017

Code Information:
a) RO846356 Exp. 8/28/2020; b) RO246852 Exp. 8/28/2020

Class II Drugs Event

Event ID:
77936

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MEDLINE INDUSTRIES INC
3 Lakes Dr
Northfield IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Vitamin A&D Ointment (petroleum 93.5%), Skin Protectant, NET Wt. 0.18 OZ (5g), Manufactured for Medline Industries, Inc., Northfield, IL 60093 USA. NDC: 53329-090-16

Product Quantity:
462 cases, 144 packets per case

Reason for Recall:
Labeling Mixup; the individual A&D ointment foil packets are incorrectly labeled as petroleum jelly. The boxes and outer case are correctly labeled as A&D ointment.

Recall Number:
D-1138-2017

Code Information:
Lot Number: A-K-8383

Class II Drugs Event

Event ID:
77959

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Bella Pharmaceuticals, Inc.
3101 W Devon Ave
Chicago IL United States

Distribution Pattern:
Nationwide within USA

Associated Products

Product Description:
PF-Glutathione 200mg/ml, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659 1 (877) BELLA.

Product Quantity:
82 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1146-2017

Code Information:
Lot #: 070617GL, Exp. 1/6/18

Product Description:
Methylcobalamin 10mg, (1mg/ml), 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
30 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1147-2017

Code Information:
Lot #: 070717MC, Exp. 1/7/18

Product Description:
Mannitol 20%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
10 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1148-2017

Code Information:
Lot #: 070717ML, Exp. 1/7/18

Product Description:
G.A.C 25/100/250mg, 30 mL Vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
3 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1149-2017

Code Information:
Lot #: 071217GAC, 1/12/18

Product Description:
Calcium chloride 10%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1150-2017

Code Information:
Lot #: 071217CC, Exp. 10/12/18

Product Description:
B-Complex, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659,1 (877) BELLA.

Product Quantity:
45 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1151-2017

Code Information:
Lot #: BPBC3080517, Exp. 2/5/18

Product Description:
Methylcobalamin 10mg, (10mg/ml), 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
7 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1152-2017

Code Information:
Lot #: BPMC30072917, Exp. 1/29/18

Product Description:
Magnesium Chloride 200mg, 30m L vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1153-2017

Code Information:
Lot #: BPMC08517, Exp. 2/5/18

Product Description:
L-Glutamine 100mg, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1154-2017

Code Information:
Lot #: BPLG08517, Exp. 2/5/18

Product Description:
MIC 25/50/50, 30mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1155-2017

Code Information:
Lot #: BPMIC30072917, Exp. 1/29/18

Product Description:
Lidocaine Ophthalmic Gel 3.5%, 15mL bottles, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659,1(877) BELLA.

Product Quantity:
6 bottles

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1156-2017

Code Information:
Lot #: BPLG3508717, Exp. 11/7/17

Product Description:
Phenylephrine2.5%/Tropicamide 1% Ophthalmic Solution, 15mL bottle, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
6 bottles

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1157-2017

Code Information:
Lot #: BPPTC08717, Exp. 11/7/17

Product Description:
Sodium Bicarbonate 8.4%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
20 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1158-2017

Code Information:
Lot #: BPSB8408717, Exp. 11/7/17

Product Description:
Fluorescein Sodium, 5mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
644 vials

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1159-2017

Code Information:
Lot #: BPFS41717, Exp. 4/1/18

Product Description:
Bevacizumab Prefilled 30g and 31 gram 1.25mg/0.05mL Syringes, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.

Product Quantity:
2,334 syringes

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1160-2017

Code Information:
Lot #: 3141201, Exp. 9/13/17; 3146966, Exp . 9/20/17; 3160608, Exp. 10/5/17; 3146966, Exp. 11/1/17

Product Description:
BevaDex (bevacizumab) 0.06mL Prefilled 32 g (1.25mg/1mg) Syringes, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659 (877) BELLA.

Product Quantity:
200 syringes

Reason for Recall:
Lack of Assurance of Sterility.

Recall Number:
D-1161-2017

Code Information:
Lot #: 08152017, Exp. 11/15/17

Class II Drugs Event

Event ID:
77963

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/18/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals USA Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide within United States

Associated Products

Product Description:
Paroxetine tablets USP, 30mg, 30-count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA, Inc., Pennington, NJ 08534, NDC 68382-099-06, UPC 3 6838209906 8

Product Quantity:
44800 bottles

Reason for Recall:
Presence of Foreign tablets/capsules: risperidone Tablets were found in bottle of paroxetine Tablets

Recall Number:
D-1137-2017

Code Information:
Lot #: Z701133, Exp 03/19

Class II Drugs Event

Event ID:
77990

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Centurion Labs, LLC
3100 Bowling Dr Suite 1
Birmingham AL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Ninjacof (Chlophedianol HCL 12.5 mg and Pyrilamine Maleate 12.5 mg) Oral Solution, 16 fl. oz. (473 mL), Cotton Candy Flavor, Manufactured for: Centurion Labs, LLC Birmingham, AL 35243 --- NDC 23359-032-16

Product Quantity:
4149 bottles

Reason for Recall:
Microbial contamination of Non-sterile Products; potential B. cepacia contamination

Recall Number:
D-1140-2017

Code Information:
Lot: 200N1601 Exp. 11/2018

Product Description:
Ninjacof-A (Acetaminophen 160 mg, Chlophedianol HCL 12.5 mg and Pyrilamine Maleate 12.5 mg) Oral Solution, 16 fl. oz. (473 mL), Cotton Candy Flavor, Manufactured for: Centurion Labs, LLC Birmingham, AL 35243 --- NDC 23359-033-16

Product Quantity:
621 bottles

Reason for Recall:
Microbial contamination of Non-sterile Products; potential B. cepacia contamination

Recall Number:
D-1141-2017

Code Information:
Lot: 201NA1601 Exp. 11/2018

Class II Drugs Event

Event ID:
78049

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/11/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Mid Valley Pharmaceutical
910 E Hidalgo Ave Suite 3
Raymondville TX United States

Distribution Pattern:
TX

Associated Products

Product Description:
Doctor Manzanilla Allergy & Decongestant Relief (diphenhydramine hydrochloride and phenylephrine hydrochloride) Syrup, 12.5 mg and 5 mg in each 5 mL, 4 fl oz. (118 mL) bottle, Distributed by: Midvalley Pharmaceuticals, Raymondville, TX 78580, UPC 7 62558 00204 1.

Product Quantity:
24 bottles

Reason for Recall:
CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.

Recall Number:
D-1135-2017

Code Information:
Lot: 23221701, Exp. 05/19

Product Description:
Doctor Manzanilla Cough & Cold (diphenhydramine hydrochloride and phenylephrine hydrochloride) Syrup, 12.5 mg and 5 mg in each 5 mL, 4 fl oz. (118 mL) bottle, Distributed by: Midvalley Pharmaceuticals, Raymondville, TX 78580, UPC 7 62558 00316 1.

Product Quantity:
24 bottles

Reason for Recall:
CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.

Recall Number:
D-1136-2017

Code Information:
Lot: 23221701, Exp. 05/19

Class III Drugs Event

Event ID:
77948

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories LLC
180 Summit Ave Ste 200
Montvale NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
AMLODIPINE BESYLATE TABLET, USP, 10 mg, 1000 count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India, Distributed by: Ascend Laboratories, LLC Montvale, NJ 07645, NDC 67877-217-10

Product Quantity:
1212 bottles

Reason for Recall:
PRESENCE OF FOREIGN TABLETS/CAPSULES: A 2.5 mg Amlodipine Besylate tablet was found co-mingled with 10 mg Amlodipine Besylate tablets in a bottle labeled as Amlodipine Besylate 10 mg.

Recall Number:
D-1134-2017

Code Information:
Lot #: 6142626, Exp 09/19

Class III Drugs Event

Event ID:
77998

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/12/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Hydrocodone Bitartrate and Acetaminophen Oral Solution 7.5 mg/325 mg per 15 mL (Cherry Flavored), 473 mL bottles, Rx only, Manufactured by: VistaPharm, Inc. Largo, FL 33771 ---- NDC 66689-023-16

Product Quantity:
3084 bottles

Reason for Recall:
Labeling: Not Elsewhere Classified; product is incorrectly labeled as Class III controlled substance instead of Class II controlled substance

Recall Number:
D-1139-2017

Code Information:
Lot: 494700 Exp. 10/2018

Class III Drugs Event

Event ID:
78067

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
09/13/2017

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
Distributed to the state of CA and NV.

Associated Products

Product Description:
Phentermine, USP Capsules, 15 mg, 30 count bottles, Rx only, Packaged By: Aidarex Pharmaceuticals, Corona, CA, MFG: KVK-TECH INC. Newtown. PA --- 33261-0361-30

Product Quantity:
35 bottles

Reason for Recall:
Failed Impurities/Degradation Specification; out-of-specification results for individual unknown impurities at the 30 month Room Temperature Retained Sample stability test

Recall Number:
D-1162-2017

Code Information:
Batch 47262-2, 47262-3, exp 8/31/2017; 47262-4, exp 12/30/17, 47262-5, 47262-6, 47262-7, exp 12/31/17