Enforcement Report - Week of July 19, 2017

Class I Drugs Event

Event ID:
77055

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/18/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Organic Herbal Supply
8303 Sierra College Blvd Ste 128
Roseville CA United States

Distribution Pattern:
Nationwide via internet

Associated Products

Product Description:
UPROAR All Natural Male Enhancement Herbal Dietary Supplement Capsules, supplied in 2, 4 and 10 count packages, Distributed by AH Distribution, DelRay, Beach, FL ---- UPC Code 680474229260

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0961-2017

Code Information:
All lots and package sizes

Product Description:
Cummor Natural Male Enhancement, Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Naturally Hard Supplements, Reno, NV --- UPC code #680474229116

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0962-2017

Code Information:
All lots and package sizes

Product Description:
ZRECT Male Enhancement Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 852675999451

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0963-2017

Code Information:
All lots and package sizes

Product Description:
Xrect Male Enhancement Herbal Dietary Supplement Capsules, 500 mg supplied in 2, 4 and 10 count packages, Distributed by Organic Herbal Supply, Roseville, CA ---- UPC Code 680474015795

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0964-2017

Code Information:
All lots and package sizes

Product Description:
RECTALIS Male Enhancement Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY --- UPC Code 680474228782

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0965-2017

Code Information:
All lots and package sizes

Product Description:
TORNADO Male Enhancement Herbal Dietary Supplement Capsules, Over 4000 mg value, supplied in 2, 4 and 10 count packages, Made in USA Distributed by American Health Supplements, Chicago, Illinois --- UPC Code 680474228959

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0966-2017

Code Information:
All lots and package sizes

Product Description:
ZDaily Daily Testosterone and Llibido Booster Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 680474229062

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0967-2017

Code Information:
All lots and package sizes

Product Description:
BIGnHARD Male Enhancement Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY ---- UPC Code 680474229086

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0968-2017

Code Information:
All lots and package sizes

Product Description:
ENHANCEROL Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY ---- UPC Code 680474229086

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0969-2017

Code Information:
All lots and package sizes

Product Description:
ZRECT for Women Herbal Dietary Supplement Capsules, 500 mg, supplied in 30 count packages, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 680474229055

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0970-2017

Code Information:
All lots and package sizes

Product Description:
LabidaMAX Herbal Dietary Supplement Capsules, 500 mg, supplied in 30 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY --- UPC Code 680474228904

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin

Recall Number:
D-0971-2017

Code Information:
All lots and package sizes

Class I Drugs Event

Event ID:
77336

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/25/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
AstraZeneca Pharmaceuticals, LP
587 Old Baltimore Pike
Newark DE United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico to physician offices.

Associated Products

Product Description:
BRILINTA (ticagrelor) tablets, 90 mg, 8-count Professional Sample bottles, Rx only, Mfd. for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850; By: AstraZeneca AB, SE-151 85 Sodertalje, Sweden, NDC 0186-0777-08.

Product Quantity:
40,368 bottles

Reason for Recall:
Presence of Foriegn Tablets/Capsules: customer complaint that an 8-count professional sample bottle labeled as BRILINTA 90 mg tablets contained 5 ZURAMPIC 200 mg tablets, in addition to the expected 8 BRILINTA tablets.

Recall Number:
D-0958-2017

Code Information:
Lot # JB5047, Exp 10/19

Class I Drugs Event

Event ID:
77393

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/31/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals

Distribution Pattern:
Nationwide in the US

425 Privet Rd
Horsham PA United States

Associated Products

Product Description:
Paliperidone Extended-Release Tablets, 3 mg, 90 count bottles, Rx only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314 USA Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA, NDC: 0591-3693-19

Product Quantity:
360 bottles

Reason for Recall:
Failed Dissolution Specifications: Drug release test result, obtained during routine 9-month stability testing, which was below specification for one tablet. Teva cannot at this time exclude the potential for additional tablets to be below specification.

Recall Number:
D-0960-2017

Code Information:
Lot: 1160682A, EXP. 06/18

Class I Drugs Event

Event ID:
77414

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Bristol-myers Squibb Company
1 Squibb Dr
New Brunswick NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
EliquisTablets 5mg, 60 count bottle, Rx Only, Marketed by: Bristol-Meyers Squibb Company Princeton, NJ 08543 USA and Pfizer Inc. New York, NY 10017 USA, NDC 0003-0894-21

Product Quantity:
48,180 bottles

Reason for Recall:
Labeling: Label Mix-up: One bottle of Eliquis 5 mg tablet was found to contain lower-strength Eliquis 2.5 mg tablets only instead of the labeled 5 mg tablets.

Recall Number:
D-0959-2017

Code Information:
Lot: HN0063, EXP. 09/2019

Class II Drugs Event

Event ID:
77591

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/13/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Sigan Industries Inc.
296 Orenda Rd
Brampton Canada

Distribution Pattern:
CA

Associated Products

Product Description:
CVS Health Baby Eczema Moisturizing Cream(colloidal oatmeal 1.0%), Net Wt. 7.3 oz (207g) tubes, OTC, Distributed by CVS Pharmacy Inc., Woonsocket, RI --- UPC 050428568033

Product Quantity:
19,608 tubes

Reason for Recall:
Microbial Contamination of Non Sterile Products; out of specification Total Plate Count

Recall Number:
D-0975-2017

Code Information:
lot number 17-01319, exp 01/19

Class II Drugs Event

Event ID:
77595

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/07/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Nationwide with the United States

Associated Products

Product Description:
QUELICIN (Succinylcholine Chloride) Injection, USP 20 mg/mL in a) 5 mL vial (NDC 15082-814-67), b) 7mL vial (NDC 15082-814-79), c) 10mL vial (NDC 15082-814-61), Repackaged by Advanced Pharm, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404.

Product Quantity:
2350 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0953-2017

Code Information:
Lot #: a) 5/15/17 2305 81467S, BUD 7/29/2017; 5/22/17 1000 81467S, BUD 8/5/2017; 5/30/17 1549 81467S,BUD 8/13/2017. b) 5/24/17 0307 169-81479S, BUD 7/23/2017; 5/18/17 0220 169-81479S, BUD 7/17/2017; 5/16/17 0306 169-81479S, BUD 7/15/2017; 6/5/17 0937 169-81479S, BUD 8/04/2017; 5/16/17 0314 445-81479S, BUD 7/15/2017; 5/16/17 0315 493-81479S, BUD 7/15/2017; c) 5/15/17 2119 81461S, BUD 7/29/2017; 5/22/17 0922 81461S, BUD 8/5/2017; 5/30/17 1533 81461S, BUD 8/13/2017; 6/12/17 1846 81461S, BUD 8/26/2017; 6/5/17 0237 157-81461SB, BUD 8/4/2017.

Product Description:
Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 20 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-926-25

Product Quantity:
72 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0954-2017

Code Information:
Lot #: 5/23/17 1404 299-92625P, BUD: 8/21/2017; 5/26/2017 1250 297-92625P, BUD 8/24/2017.

Product Description:
Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 30 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-924-25

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0955-2017

Code Information:
Lot #: 5/31/17 1416 382-92425P BUD: 8/29/2017

Product Description:
Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 15 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-922-25

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0956-2017

Code Information:
Lot #: 6/7/17 1446 515-92225P BUD: 9/5/2017; 6/2/17 1100 515-92225P BUD: 8/31/2017; 5/31/17 1415 382-92225P BUD: 8/29/2017.

Class II Drugs Event

Event ID:
77676

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide, Puerto Rico and United Arab Emirates

Associated Products

Product Description:
5% Dextrose Injection, USP, 100 mL VIAFLEX Plastic Container, Rx only, Baxter Healthcare Corporation, Deerfield IL 60015 USA, Product Code: 2B0089, NDC: 0338-0017-38

Product Quantity:
54,528 bags

Reason for Recall:
Lack of Assurance of Sterility: Bags have the potential to leak.

Recall Number:
D-0972-2017

Code Information:
Lot: P361618, Exp 09/30/18;

Product Description:
0.9% Sodium Chloride Injection, USP, 100 mL VIAFLEX Container, Rx Only, Baxter Healthcare Corporation, Deerfield IL 60015 USA, Product Code: 2B1309, NDC: 0338-0049-38

Product Quantity:
295,200 bags

Reason for Recall:
Lack of Assurance of Sterility: Bags have the potential to leak.

Recall Number:
D-0973-2017

Code Information:
Lots: P361501, P361667, and P361790, Exp 09/30/18

Class II Drugs Event

Event ID:
77678

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/07/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide in USA

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP, 250 mL VIAFLEX Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015; Distributed in Canada by Baxter Corporation, Toronto, Ontario, Canada, Product Code: 2B1322, NDC 0338-0049-02.

Product Quantity:
131,904 bags

Reason for Recall:
Lack of Assurance of Sterility: Customer complaints for leaking bags.

Recall Number:
D-0957-2017

Code Information:
Lot: Y229153, Exp 09/30/18

Class III Drugs Event

Event ID:
77606

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/12/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Paroxetine Extended-Release Tablets USP, 12.5 mg, 30 count bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland, 21202, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, India, NDC: 68180-647-06

Product Quantity:
12480 bottles

Reason for Recall:
Failed Dissolution Specifications: out of specification observed in dissolution testing at 3 month long term stability study.

Recall Number:
D-0974-2017

Code Information:
Lots: H605712, H605711, H605710, EXP November 2018; H702255, H702202 EXP March 2019