Enforcement Report - Week of August 23, 2017

Class I Drugs Event

Event ID:
77208

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/15/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Genetic Edge Compounds LLC
2305 Brandywine
McKinney TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
GEC LX Laxoplex 60 capsules Dietary Supplement, 60 count bottle, Manufactured by GEC, McKinney, TX, 75070, UPC: 700580499842

Product Quantity:
1759 bottles (105, 540 capsules)

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplement: FDA analysis found the product to tainted with undeclared anabolic steroids and steroid like substances.

Recall Number:
D-1092-2017

Code Information:
All lots.

Class I Drugs Event

Event ID:
77323

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/15/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Limited (Unit 1)
Unit 1, Plot 2, SEZ, Phase II, Misc Zone Apparel Park, Dist. Dhar
Pithampur India

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Mibelas 24 Fe (Norethindrone acetate and Ethinyl estradiol 1 mg/0.02 mg chewable and ferrous Fumarate 75 mg) Tablets, wallet of 28 tablets (NDC 68180-911-11), Carton of 3 wallets (NDC 68180-911-13), Rx Only, Manufactured by: Lupin Limited, India, Distributed by Lupin Pharmaceuticals, Inc., Baltimore, MD, 21202

Product Quantity:
24,652 tablets

Reason for Recall:
Contraceptive Tablets Out of Sequence- First 4 pills of the packet are brown, instead of the last four pills and the expiry/lot was not printed on the package.

Recall Number:
D-1093-2017

Code Information:
Batch Number L600518; Exp. 05/18

Class I Drugs Event

Event ID:
77333

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2017

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:
DYNAMIC TECHNICAL FORMULATIONS
660 Hembree Pkwy Ste 115
Roswell GA United States

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Biotech Underground Tri-Ton Hardcore Formula capsules, 90-count bottle, Distributed by: Dynamic Technical Formulations 12850 Hwy 9 Suite 600-441 Alpharetta, GA 30004

Product Quantity:
728 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplement: Product was tested by FDA and found to contain andarine and ostarine.

Recall Number:
D-1087-2017

Code Information:
All lots

Class I Drugs Event

Event ID:
77660

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
HARDCORE FORMULATIONS
3012 Fm 621 Ste B
San Marcos TX United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
ULTRA-STEN Rapid Size and Strength capsules, 10 mgs, 90 count bottle, Hardcore Formulations UPC: 7 48252 68763 0

Product Quantity:
1490 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Product contains Methylstenbolone or Dymethazine.

Recall Number:
D-1084-2017

Code Information:
All lots remaining within expiry.

Product Description:
D-ZINE Rapid Size and Strength capsules, 10mgs, 90 count bottle, Hardcore Formulations, UPC: 7 48252 86193 1

Product Quantity:
1440 bottles

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Product contains Methylstenbolone or Dymethazine.

Recall Number:
D-1085-2017

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
77357

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/17/2017

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

Recalling Firm:
Global Marketing Enterprises, Inc.

Distribution Pattern:
KY, VA, MI

1801 S Canal St
Chicago IL United States

Associated Products

Product Description:
Caffeine Powder, Anhydrous, Pharmaceutical Grade, 100% Pure caffeine, 250 g (8.8 oz)., 1250 servings, Packed By: LifeLine Nutrients Corp, 1801 S. Canal St, Chicago, IL 60616, UPC 021754905076

Product Quantity:
52.5 kg

Reason for Recall:
Marketed without an Approved NDA/ANDA: The product consists of pure, powdered caffeine and is an unapproved drug due to stimulant claims. The product is also misbranded as it fails to bear adequate directions for its intended use.

Recall Number:
D-1096-2017

Code Information:
Batch # 15121931, 15121939, Exp 12/19

Class II Drugs Event

Event ID:
77824

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
ICU Medical Inc
600 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
0.9% Sodium Chloride Injection, USP in 1000 mL Single Dose Flexible Container, Hospira, Inc., Lake Forest, IL 60045 USA --- NDC# 0409-7983-09

Product Quantity:
436,716 flexible containers

Reason for Recall:
Presence of Particulate Matter; stainless steel

Recall Number:
D-1091-2017

Code Information:
Lot: 61-841-FW Exp. 01/01/2018

Class II Drugs Event

Event ID:
77889

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amgen, Inc.
1 Amgen Center Dr
Thousand Oaks CA United States

Distribution Pattern:
United States including Puerto Rico

Associated Products

Product Description:
Procrit Epoetin Alfa 40,000 units/mL single use vial For Intravenouse or Subcutaneous Use Only, Rx only, Manufactured by: Amgen Inc., Thousand Oaks, CA 91320-1799, Manufactured for: Janssen Products, LP Horsham, PA 19044, NDC 59676-340-01

Product Quantity:
175,632 vials

Reason for Recall:
Presence of particulate matter: Visible glass flakes identified as lamellae in some drug product vials.

Recall Number:
D-1086-2017

Code Information:
Lot #: G290491A, G290491B, Exp. 06/18

Class III Drugs Event

Event ID:
77800

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/15/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Voriconazole Tablets, 200 mg, 20-count cartons (4 x 5) Unit Dose, Rx only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 50268-804-12

Product Quantity:
1172 cartons (23440 tablets)

Reason for Recall:
Failed impurities/degradation specifications: Out of specification for a related compound C.

Recall Number:
D-1094-2017

Code Information:
Lot #: 16933, Exp 07/2018; 17054, Exp 08/2018

Class III Drugs Event

Event ID:
77822

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Chlorhexidine Gluconate Oral Rinse, 0.12%, 15 mL Unit Dose Cup, a) unit dose cup (NDC 50383-720-15), b) 100-count tray (NDC 50383-720-19), Rx Only, Hi-Tech Pharmacal Co. Inc., Amityville, NY 11701.

Product Quantity:
541,900 unit dose cups (5,419 trays)

Reason for Recall:
Crystallization with subpotent out of specification assay results for chlorhexidine.

Recall Number:
D-1088-2017

Code Information:
Lot: 353394, Exp 10-2018

Product Description:
Halyard 24-Hour Oral Care Kit q2, contains 2x15 mL Unit Dose Cups 0.12% Chlorhexidine Gluconate Oral Rinse. Manufactured by Halyard Health Inc., 5405 Windward Parkway, Alpharetta, GA 30004. Distributed by Halyard Sales, LLC Alpharetta, GA 30004. REF # 97012

Product Quantity:
40,978 unit dose cups

Reason for Recall:
Crystallization with subpotent out of specification assay results for chlorhexidine.

Recall Number:
D-1089-2017

Code Information:
Lots: 0202623109, 0202623110, 0202623111, 0202630207, 0202630208, 0202630209, EXP 06-2018; 0202642227, 0202642228, 0202647413, 0202647414, 0202653433, 0202653434, EXP 07-2018.

Product Description:
Halyard 24-Hour Oral Care Kit q4, contains 2x15 mL Unit Dose Cups 0.12% Chlorhexidine Gluconate Oral Rinse. Manufactured by Halyard

Product Quantity:
101,952 15 mL unit dose cups

Health Inc., 5405 Windward Parkway, Alpharetta, GA 30004. Distributed by Halyard Sales, LLC Alpharetta, GA 30004. REF # 97014

Reason for Recall:
Crystallization with subpotent out of specification assay results for chlorhexidine.

Recall Number:
D-1090-2017

Code Information:
Lots: 0202635072, 0202635073, EXP 06-2018; 0202630205, 0202630206, EXP 07-2018; 0202630203, 0202630204, 0202642217, 0202642218, 0202642219, 0202647410, 0202647411, EXP 08-2018; 0202647409, 0202647412, 0202653431, 0202653432, EXP 09-2018.

Class III Drugs Event

Event ID:
77840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/17/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Linde Eckstein Gmbh + Co KG
Flurstrasse 27a-35
Oberasbach Germany

Distribution Pattern:
Distributed throughout the United States

Associated Products

Product Description:
Beautipharm All Day Moisturizing Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Facial Cream, 1.66 oz. Net. Wt. 50 ml bottle, Art. 03120 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 032005.

Product Quantity:
478 balms

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1097-2017

Code Information:
Lot #: 240817, Exp 08/24/17; 061217, Exp 12/06/17; 290318, Exp 03/29/18; 160818, Exp 08/16/18; 231118, Exp 11/23/18; 160119, Exp 01/16/19; 080819, Exp 08/08/19

Product Description:
Beautipharm Body Moisturizing Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Body Lotion, 8.3 oz. Net. Wt. 250 ml bottle, Art. 03150 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 031503.

Product Quantity:
105 creams

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1098-2017

Code Information:
Lot #: 201017, Exp 10/20/17; 290618, Exp 06/29/18; 040419, Exp 04/04/19.

Product Description:
Beautipharm Eye Care Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Eye cream, 1 oz. Net. Wt. 30 ml bottle, Art. 03190 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 031909.

Product Quantity:
73 balms

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1099-2017

Code Information:
Lot #: 280318, Exp 03/28/2018; 020918, Exp 09/02/2018; 131019, Exp 10/13/19

Product Description:
Make Up Transparent ivory (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03200, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032005.

Product Quantity:
373 creams

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1100-2017

Code Information:
Lot #: 180318, Exp 03/18/2018

Product Description:
Make Up Transparent pastel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03210, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032104.

Product Quantity:

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1101-2017

Code Information:
Lot #: 130917, Exp 09/13/2017; 310318, Exp 03/31/2018; 270718, Exp 07/27/2018; 081118, Exp 11/08/2018.

Product Description: **Product Quantity:**
Make Up Transparent sand (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03220, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032203.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1102-2017

Code Information:
Lot #: 300817, Exp 08/30/2017; 291217, Exp 12/29/2017; 010918, Exp 09/01/2018.

Product Description: **Product Quantity:**
Make Up Perfect caramel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03330, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032302.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1103-2017

Code Information:
Lot #: 130917, Exp 09/13/2017; 010818, Exp 08/01/2018.

Product Description: **Product Quantity:**
Make Up Transparent dark tan (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03240, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032401.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1104-2017

Code Information:
Lot #: 040318, Exp 03/04/2018; 261018, Exp 10/26/2018.

Product Description: **Product Quantity:**
Make Up Transparent terra (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03250, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032500.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1105-2017

Code Information:
Lot #: 060917, Exp 09/06/2017.

Product Description: **Product Quantity:**
Make Up Perfect ivory (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03300, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033002.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1106-2017

Code Information:
Lot #: 310318, Exp 03/31/2018.

Product Description: **Product Quantity:**
Make Up Perfect pastel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03310, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033101.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1107-2017

Code Information:
Lot #: 210917, Exp 09/21/2017; 010918, Exp 09/01/2018.

Product Description: **Product Quantity:**
Make Up Perfect sand (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03320, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033200.

Reason for Recall: **Recall Number:**
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed. D-1108-2017

Code Information:
Lot #: 200917, Exp 09/20/2017; 230218, Exp 02/23/2018; 010918, Exp 09/01/2018; 140219, Exp 02/14/2019.

Product Description: **Product Quantity:**
Make Up Perfect dark tan (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03340, Made in Germany, Doctor Eckstein,

Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033408.

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1109-2017

Code Information:
Lot #: 310318, Exp 03/31/2018; 180718, Exp 07/18/2018; 020219, Exp 02/02/2019.

Product Description:
Make Up Perfect terra (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03350, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033507.

Product Quantity:

Reason for Recall:
Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.

Recall Number:
D-1110-2017

Code Information:
Lot #: 221217, Exp 12/22/2017; 270718, Exp 07/27/2018.

Class III Drugs Event

Event ID:
77878

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/11/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Nationwide in the United States

Associated Products

Product Description:
Phentermine HCL Capsules, USP 15 mg, packaged in a) 100-count bottles (NDC 10702-026-01), and b) 1000-count bottles (NDC 10702-026-10), Rx only, mfd. by: KVK-TECH, INC. NEWTOWN, PA 18940

Product Quantity:
35,267 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: out-of-specification results obtained for individual unknown impurities found at 30 month Room Temperature Retained Sample stability test.

Recall Number:
D-1083-2017

Code Information:
Lot # a):12322A, 12323B, 12324A, Exp. Sep 2017; 12455A, Exp. Dec 2017; b) 12323A, Exp. Sep 2017; 12456A, Exp. Dec 2017