Enforcement Report - Week of January 17, 2018

Class II Drugs Event

Event ID:
78369

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medex Cardio-Pulmonary Inc., d.b.a. Smiths Medical Company
330 Corporate Woods Pkwy
Vernon Hills IL United States

Distribution Pattern:
IA, WI

Associated Products

Product Description:
Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 1 oz. 144 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061 Model Number: 32-005582.

Product Quantity:
29,232 1 oz bottle

Reason for Recall:
Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.

Recall Number:
D-0157-2018

Code Information:
Lot: Z516

Product Description:
Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 4 oz. 24 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005583

Product Quantity:
22,080 4 oz bottles

Reason for Recall:
Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.

Recall Number:
D-0158-2018

Code Information:
Lot: A225

Product Description:
Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 16 oz. 12 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005585

Product Quantity:
130,740 16 oz bottles

Reason for Recall:
Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.

Recall Number:
D-0159-2018

Code Information:
Lot: A259, A260, EXP 05-26-2018; A301, 06-23-2018; B117, B118, EXP 03-02-2019; C005, EXP 01-09-2020; C219, EXP 05-24-2020; Z521, EXP 10-06-2017

Product Description:
Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 32 oz. 12 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005587

Product Quantity:
96,828 32 oz bottles

Reason for Recall:
Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.

Recall Number:
D-0160-2018

Code Information:
Lot: A257, EXP 05-20-2018; A258, EXP 05-19-2018; B017, EXP 01-12-2019; B116, B119, EXP 05-03-2019; B120, EXP 05-04-2019; B131, EXP 05-05-2019; Z535, EXP 10-13-2017; Z638, EXP 12-19-2017.

Class II Drugs Event

Event ID:
78553

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KRS Global Biotechnology, Inc
791 Park of Commerce Blvd Ste 600
Boca Raton FL United States

Distribution Pattern:
Nationwide in the USA, Bermuda, and New Zealand

Associated Products

Product Description:
Anastrozole 0.5 mg Capsules, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
15,700 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0161-2018

Code Information:
Lots: 03092017@21 BUD: 3/9/2018; 03292017@33 BUD: 3/24/2018; 05092017@38 BUD: 5/4/2018; 05162017@31 BUD: 5/11/2018; 05182017@25 BUD: 5/13/2018; 07032017@40 BUD: 6/28/2018; 07142017@34 BUD: 7/9/2018; 07192017@32 BUD: 7/14/2018; 08282017@25 BUD: 8/23/2018; 09142017@8BUD: 9/9/2018; 09212017@23 BUD: 9/16/2018; 09272017@36 BUD: 9/ 22/2018; 10162017@39 BUD: 10/11/2018; 11032017@28 BUD: 10/29/2018

Product Description:
Amphotericin 60 mg/Chloramphenicol 600 mg/Hydrocortisone 10 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
80 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0162-2018

Code Information:
Lot: 07282017@25 BUD: 1/24/2018

Product Description:
Anastrozole SR 1 mg Capsules, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
22,520 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0163-2018

Code Information:
Lots: 02022017@30 BUD: 1/28/2018; 04172017@29 BUD: 4/12/2018; 05082017@39 BUD: 5/3/2018; 05222017@23 BUD: 5/17/2018; 06072017@28 BUD: 6/2/2018; 06122017@42 BUD: 6/7/2018; 06192017@24 BUD: 6/14/2018; 06292017@25 BUD: 6/24/2018; 07112017@33 BUD: 7/6/2018; 07172017@35 BUD: 7/12/2018; 07282017@26 BUD: 7/23/2018; 08012017@25 BUD: 7/27/2018; 08112017@35 BUD: 8/9/2018; 08142017@30 BUD: 8/9/2018; 08172017@31 BUD: 8/12/2018; 09202017@21 BUD: 9/15/2018; 09142017@27 BUD: 9/9/2018; 10022017@38 BUD: 3/31/2018; 10102017@37 BUD: 4/8/2018; 10172017@26 BUD: 4/15/2018; 10202017@22 BUD: 4/18/2018; 10302017@29 BUD: 4/28/2018

Product Description:
Arginine 150 mg/ Lysine HCl 50 mg/ Glutamine 200 mg/g Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.

Product Quantity:
490 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0164-2018

Code Information:
Lot: 05242017@54 BUD: 11/20/2017

Product Description:
Benzocaine 20%, Lidocaine 6%, Tetracaine 4% Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
4,530 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0165-2018

Code Information:
Lots: 06072017@22 BUD: 12/4/2017; 06222017@30 BUD: 12/19/2017; 08032017@31 BUD: 1/30/2018; 09212017@21 BUD: 3/20/2018; 10232017@20 BUD: 11/22/2017

Product Description:
Benzocaine 20%, Lidocaine 8%, Tetracaine 4% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
1,380 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0166-2018

Code Information:
Lots: 07142017@31 BUD: 1/10/2018; 09202017@22 BUD: 3/19/2018; 10042017@25 BUD: 4/2/2018

Product Description:
Benzo/Lido/Tetracaine 20%-8%-8% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
3,280 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0167-2018

Code Information:
Lots: 06072017@38 BUD: 12/4/2017; 07062017@48 BUD: 1/2/2018; 08012017@23 BUD: 1/28/2018; 08212017@36 BUD: 2/17/2018; 09182017@26 BUD: 3/17/2018

Product Description:
Bi-Est (Estriol/Estradiol) (80/20) + Progesterone 7.5 mg/200 mg Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.

Product Quantity:
300 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0168-2018

Code Information:
Lot: 08172017@39 BUD: 12/15/2017

Product Description:
Chloramphenicol 50 mg/ Sulfamethoxazole 50 mg/ Amphotericin-B 5 mg capsules, For OTIC Use Only, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
90 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0169-2018

Code Information:
Lot: 08212017@24 BUD: 2/17/2018

Product Description:
Chloramphenicol 500 mg Amphotericin 50 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
20 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0170-2018

Code Information:
Lot: 08162017@32 BUD: 2/12/2018

Product Description:
Chloramphenicol 500 mg Sulfamethoxazole 500 mg Amphotericin 50 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
100 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0171-2018

Code Information:
Lots: 07282017@24 BUD: 1/24/2018; 08162017@33 BUD: 2/12/2018

Product Description:
Estriol 0.1% (1 mg/gm) Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
300 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0172-2018

Code Information:
Lot: 07182017@45 BUD: 1/14/2018

Product Description:
Human Chorionic Gonadotropin 500 iu Orally Disintegrating Tablets (ODT), Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
2,239 tablets

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0173-2018

Code Information:
Lot: 06132017@22 BUD: 12/10/2017

Product Description:
Human Chorionic Gonadotropin 2,500 Units, Vial-Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
1,203 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0174-2018

Code Information:
Lots: 06212017@19 BUD: 12/18/2017; 10052017@1 BUD: 4/3/2018

Product Description:
Human Chorionic Gonadotropin 5,000 iu/ Vial Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
6,414 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0175-2018

Code Information:
Lots: 06132017@2 BUD: 12/10/2017; 07262017@17 BUD: 1/22/2018; 10032017@1 BUD: 4/1/2018

Product Description:
Human Chorionic Gonadotropin 6,000 iu/Vial, For SC Use -Lyophilized, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
2,239 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0176-2018

Code Information:
Lot: 08302017@11 BUD: 2/26/2018

Product Description:
Human Chorionic Gonadotropin 11,000 iu/Vial Lyophilized For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
7,862 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0177-2018

Code Information:
Lots: 06222017@10 BUD: 12/19/2017; 09272017@14 BUD: 3/26/2018; 05312017@5 BUD: 11/27/2017; 07192017@8 BUD: 1/15/2018

Product Description:
Human Chorionic Gonadotropin 20,000 iu/Vial, Lyophilized - For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
2,274 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0178-2018

Code Information:
Lots: 06082017@33 BUD: 12/5/2017; 06152017@4 BUD: 12/12/2017; 07272017@4 BUD: 1/23/2018; 10042017@22 BUD: 4/2/2018; 09282017@3 BUD: 3/27/2018

Product Description:
Hydroquinone 8%/ Tretinoin 0.1% Topical Ointment packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
30 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0179-2018

Code Information:
Lot: 08222017@37 BUD: 11/20/2017

Product Description:
Hydroxocobalamin 0.5 mg/mL For Diluent Purpose Only 10 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
1,009 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0180-2018

Code Information:
Lot: 10102017@9 BUD: 2/7/2018

Product Description:
Hydroxocobalamin 1 mg/mL 30 mL Vial For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
596 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0181-2018

Code Information:
Lot: 10162017@20 BUD: 2/13/2018

Product Description:
Iodochlorhydroxyquin 3%/ Boric Acid 10%/ Amphotericin 5% Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
40 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0182-2018

Code Information:
Lot: 07282017@23 BUD: 1/24/2018

Product Description:
Liothyronine SR (T3) 20 mcg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.

Product Quantity:
970 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0183-2018

Code Information:
Lots: 05022017@24 BUD: 4/27/2018; 10122017@21 BUD: 4/10/2018; 11062017@38 BUD: 5/5/2018; 08252017@28 BUD: 8/20/2018

Product Description:
Methylene Blue (PF) 10 mg/mL (1%) Injectable Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
696 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0184-2018

Code Information:
Lot: 09252017@7 BUD: 12/24/2017

Product Description:
Nicotinamide Adenine Dinucleotide 500 mg packaged in vials, Lyophilized-For IV Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
2,535 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0185-2018

Code Information:
Lot: 06062017@3 BUD: 12/3/2017

Product Description:
Oxytocin 30 Units in 0.9% Sodium Chloride Solution (PF) IV Bag, For IV Infusion Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
963 bags

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0186-2018

Code Information:
Lots: 10112017@10 BUD: 1/9/2018; 10252017@9 BUD: 1/23/2018

Product Description:
PrednisoLONE 10 mg Tablet, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
3,000 tablets

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0187-2018

Code Information:
Lot: 07172017@40 BUD: 1/13/2018

Product Description:
Progesterone 3% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
300 jars

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0188-2018

Code Information:
Lot: 09212017@22 BUD: 3/20/2018

Product Description:
QUADMIX #16, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
126 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final

Recall Number:
D-0189-2018

product.

Code Information:
Lot: 05242017@25 BUD: 11/20/2017

Product Description:
QUADMIX #17, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
122 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0190-2018

Code Information:
Lot: 05242017@27 BUD: 11/20/2017

Product Description:
QUADMIX #18, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
129 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0191-2018

Code Information:
Lot: 05242017@29 BUD: 11/20/2017

Product Description:
Savinase 100 mcg/mL Topical Solution, 1 mL in a 3 mL Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
30 droptainers

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0192-2018

Code Information:
Lot: 06262017@31 BUD: 6/26/2018

Product Description:
Sermorelin 500 mcg Orally Disintegrating Tablets (ODT), Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
3,000 tablets

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0193-2018

Code Information:
Lot: 07112017@32 BUD: 1/7/2018

Product Description:
Sermorelin, 3 mg/ GHRP6, 1.8 mg/ GHRP2, 1.8 mg/mL in 3 mL Cartridge, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
80 cartridges

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0194-2018

Code Information:
Lot: 10122017@8 BUD: 2/9/2018

Product Description:
Sermorelin, 3 mg/ GHRP6, 3 mg/GHRP2, 3 mg, Vial - Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
597 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0195-2018

Code Information:
Lots: 06162017@12 BUD: 12/13/2017; 08042017@1 BUD: 1/31/2018

Product Description:
Sermorelin Acetate 3 mg/ GHRP6 3 mg, Lyophilized Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
157 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0196-2018

Code Information:
Lot: 06272017@4 BUD: 12/24/2017

Product Description:
Sincalide 5 mcg Lyophilized Vials, For IV Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
898 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0197-2018

Code Information:
Lot: 07052017@2 BUD: 1/1/2018

Product Description:
Trimix #22F (Prostaglandin E1 25 mcg/ Papaverine HCl 30 mg/ Phentolamine Mesylate 2 mg/mL), For Intracavernous Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
235 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0198-2018

Code Information:
Lot: 05262017@21 BUD: 11/22/2017; 07132017@2 BUD: 1/9/2018

Product Description:
Trimix #23F (Prostaglandin E1 6 mcg/ Papaverine HCl 17.8 mg/ Phentolamine Mesylate 0.6 mg/mL), For Intracavernous Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
94 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0199-2018

Code Information:
Lot: 06142017@6 BUD: 12/11/2017

Product Description:
T-105 (Prostaglandin E1, 10 mcg/ Papaverine 30 mg/ Phentolamine 1 mg/mL), For Intracavernouse Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
173 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0200-2018

Code Information:
Lot: 07122017@2 BUD: 1/8/2018

Product Description:
Cyclopentolate HCl/ Phenylephrine HCl/ Tropicamide/ Ketorolac 1%/ 2.5%/ 1%/ 0.5% Ophthalmic Solution, 3 mL Multi Dose Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
297 droptainers

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0201-2018

Code Information:
Lot: 09192017@20 BUD: 12/18/2017

Product Description:
Cyclopentolate HCl/ Phenylephrine HCl/ Tropicamide/ Ketorolac 1%/ 10%/ 1%/ 0.5% Ophthalmic Soln, 5 mL Multi Dose Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
81 droptainers

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0202-2018

Code Information:
Lot: 10042017@34 BUD: 1/2/2018

Product Description:
Vitamin 9 Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
479 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0203-2018

Code Information:
Lot: 07102017@4 BUD: 1/6/2018

Product Description:
Vitamin 9 A/B Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
3612 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0204-2018

Code Information:
Lots: 06092017@2 BUD: 12/6/2017; 07212017@16 BUD: 1/17/2018; 07312017@26 BUD: 1/27/2018; 08182017@5 BUD: 2/14/2018; 09222017@2 BUD: 3/21/2018; 09292017@2 BUD: 3/28/2018; 10062017@2 BUD: 4/4/2018

Product Description:
Vitamin 10 B Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
5786 vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0205-2018

Code Information:
Lots; 05232017@13 BUD: 11/19/2017; 05262017@2 BUD: 11/22/2017; 06022017@1 BUD: 11/29/2017; 06092017@1 BUD: 12/6/2017; 06162017@10 BUD: 12/13/2017; 08142017@10 BUD: 2/10/2018; 08252017@1 BUD: 2/21/2018; 09222017@1 BUD: 3/21/2018; 09292017@1 BUD: 3/28/2018; 10062017@1 BUD: 4/4/2018; 10132017@2 BUD: 4/11/2018

Product Description:
7-Ketodehydroepiandrosterone (7-Keto DHEA) 100 mg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
90 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0206-2018

Code Information:
Lot: 08012017@35 BUD: 1/28/2018

Product Description:
7-Keto DHEA 25mg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.

Product Quantity:
90 capsules

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.

Recall Number:
D-0207-2018

Code Information:
Lot: 06082017@36 BUD: 12/5/2017

Class II Drugs Event

Event ID:
78651

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Prinston Pharmaceutical Inc
2002 Eastpark Blvd
Cranbury NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Valsartan Tablets, USP, 160 mg, 90-count bottles, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd, Xunqiao, Linhai, Zhejiang 317024, China; Distributed by: Solco Healthcare US, LLC, Cranbury, NJ 08512, USA; NDC 43547-369-09.

Product Quantity:
21,987 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: confirmed customer complaint of thicker and heavier tablets in bottle.

Recall Number:
D-0209-2018

Code Information:
Lot #: 343B17025, Exp 03/31/19

Class II Drugs Event

Event ID:
78652

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ALLERGAN
1 Giralda Farms
Madison NJ United States

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Viokace (pancrelipase) tablets, 20,880 USP units, 100-count bottle, Rx only, Distributed by; Allergan USA Inc., Irvine, CA 92612, Manufactured in Canada, NDC 58914-117-10

Product Quantity:
12,699 bottles

Reason for Recall:
Subpotent Drug: One lot of Viokace is being recalled since product stability testing results did not meet the specifications for enzyme profile.

Recall Number:
D-0154-2018

Code Information:
Lot #: 160741A, Exp 02/18

Class II Drugs Event

Event ID:
78682

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/27/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Manufacturing Deutschland GmbH
Pfizer GmbH Arzneimittelwerk Godecke (Betriebsstatte Freiburg)
Freiburg im Breisgau Germany

Distribution Pattern:
Germany; products were packaged at the Pfizer Manufacturing Deutshland Gmbh location and then distributed to other countries. No product distributed in the United States or its territories.

Associated Products

Product Description:
FOR EXPORT ONLY Atorvastatin calcium Film-Coated Tablets a) 80 mg SMT Tabs Bulk, b) 40 mg SMT G EP PR KR, c) 20 mg SMT G EP PR, d) 20 mg SMT G EP PR KR, FOR MANUFACTURING, PROCESSING OR REPACKAGING

Product Quantity:
a)7387263 tablets; b)5877188 tablets; c)11755825 tablets; d) 5872816 tablets

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-0212-2018

Code Information:
Bulk Product Batch # (Packaged Lot#) a) S55350 Exp. 20 APR 2018, S55378 Exp. 07 MAR 2018, S55386 Exp. 14 MAR 2018, S53284 Exp.14 FEB 2018, S53283 Exp. 10 FEB 2018; b) S53287 Exp. 16 FEB 2018, S33417 Exp. 03 FEB 2018; c) S33445 Exp. 17 FEB 2018, S33452 Exp. 24 FEB 2018; d) S33397 Exp. 07 FEB 2018

Class II Drugs Event

Event ID:
78697

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Solco Healtcare US LLC
2002 Eastpark Blvd Ste A
Cranbury NJ United States

Distribution Pattern:
Product was distributed in Mason, OH.

Associated Products

Product Description:
Gabapentin Tablets, USP, 800 mg, 500-count, Rx only, Made in India, PONDRUGS/16 134193, Distributed by: Solco Healthcare US, LLC, Cranbury, NJ, 08512, USA. NDC 43547-0333-50

Product Quantity:

Reason for Recall:
Labeling: Label Mix-Up.some bottles labeled as Gabapentin 800 mg contain Gabapentin 600 mg

Recall Number:
D-0155-2018

Code Information:
Lot # 7700656A

Class II Drugs Event

Event ID:
78708

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals

Distribution Pattern:
U.S.A. Nationwide

8821 Knoedl Ct
Little Rock AR United States

Associated Products

Product Description:
Ephedrine sulfate 5 mg/mL in 0.9% Sodium Chloride 10 mL in Single Dose Syringe, Total Volume 10 mL, Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0600-12

Product Quantity:
1248 syringes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date - product label was missing lot number and beyond use date.

Recall Number:
D-0156-2018

Code Information:
Lot#: 20171013@30, Exp 12/27/2017

Class II Drugs Event

Event ID:
78753

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Moexipril Hydrochloride and Hydrocholorothiazide Tablets USP, 7.5 mg/12.5 mg, 100-count bottle, Rx only, Distributed By: TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC 0093-5213-01.

Product Quantity:
4,969 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: High out of specification test result for the Moexipril Diketopiperazine impurity was obtained during routine stability testing.

Recall Number:
D-0208-2018

Code Information:
Lot # 30229439A, Exp 12/17

Class II Drugs Event

Event ID:
78757

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/12/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Woodfield Pharmaceutical, LLC
10863 Rockley Rd
Houston TX United States

Distribution Pattern:
Texas

Associated Products

Product Description:
Codeine-Guaifenesin Oral Solution 10-100 mg/5 mL Antitussive Expectorant ,16 fl. oz. , Manufactured For: Method Pharmaceuticals, LLC Arlington, TX 76006, NDC 58657-500-16

Product Quantity:
15,707 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: potentially contamination with the bacteria Burkholderia cepacia

Recall Number:
D-0210-2018

Code Information:
Lot: 08616; Exp. 07/18

Class II Drugs Event

Event ID:
78842

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

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:
Distributed nationwide in the USA, Uzbekistan, and Myanmar

Associated Products

Product Description:
Docetaxel Injection USP, 20 mg/mL, One-Vial Formulation, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046 INDIA, NDC 43598-611-11

Product Quantity:
1,051 vials

Reason for Recall:
Defective Container: Product complaints received of defect in the seal of the Docetaxel injection vials that the aluminum seal and/or stopper is removed when the cap is flipped off.

Recall Number:
D-0213-2018

Code Information:
Lot #: H7044, Exp 05/19

Class III Drugs Event

Event ID:
78637

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/05/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/05/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sanofi-Aventis U.S. LLC
55 Corporate Dr
Bridgewater NJ United States

Distribution Pattern:
Distributed nationwide.

Associated Products

Product Description:
Enoxaparin Sodium, Injection 120 mg/0.8 mL, pre-filled, packaged in 10-count cartons, Rx Only, Winthrop US., a business of Sanofi-aventis, U.S. LLC Bridgewater, NJ 08807, NDC 0955-1012-10

Product Quantity:
11,474 cartons of 10 syringes per carton

Reason for Recall:
Labeling: Label Error on Declared Strength. A single syringe labeled as 150 mg/1.0 mL was found packaged in a blister labeled as 120 mg/mL

Recall Number:
D-0153-2018