Enforcement Report - Week of April 24, 2019

Class I Drugs Event

Event ID:
82584

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/05/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/22/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Brian P. Richardson
3410 Delafield Ln
Dallas TX United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Kopi Jantan Tradisional Natural Herbs Coffee, 13g individual packages, Manufactured By: Fikrysz (M) Sdn. Bhd., Kedah, Malaysia, UPC 9 557205 060083.

Product Quantity:
6000 packages

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found this product to be tainted with undeclared sildenafil and tadalafil, two FDA approved drugs for the treatment of male erectile dysfunction, making this an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Recall Number:
D-1206-2019

Code Information:
All Lots labeled with EXP 13 10 2020

Class II Drugs Event

Event ID:
82421

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/12/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/15/2019

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
MSM Nutraceuticals, LLC
2103 W Parkside Ln Ste 107
Phoenix AZ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
15% MSM, Eye Drops, Net Wt. 30ml, 1.014 oz., Manufactured by: MSM Nutraceuticals, LLC 2103 West Parkside Lane, Ste.107, Phoenix, AZ 85027, UPC 8 54582 00120 3.

Product Quantity:
5000 30 ml bottles

Reason for Recall:
Lack of Assurance of Sterility: Product is not terminally sterialized and not tested per USP 71.

Recall Number:
D-1126-2019

Code Information:
Lot # 1808051, Exp. Date 01/01/22

Product Description:
Dry Eye, Eye Drops, Active Ingredients: OptiMSM, Glycerin USP, Hyaluronic Acid, Polyethylene Glycon, Net Wt. 15ml, 0.51 fl oz., Manufactured by: MSM Nutraceuticals, LLC, UPC 8 54582 00119 7.

Product Quantity:
200 15ml bottles

Reason for Recall:
Lack of Assurance of Sterility: Product is not terminally sterialized and not tested per USP 71.

Recall Number:
D-1127-2019

Code Information:
Lot # 1808051, Exp. Date 01/01/22

Product Description:
Red Eye, Eye Drops, Active Ingredients: OptiMSM, Glycerin USP, Hyaluronic Acid, Naphazolene Chloride, Net Wt. 15ml, 0.15 fl oz., Manufactured by: MSM Nutraceuticals, LLC , UPC 8 54582 00118 0

Product Quantity:
200 15 ml Bottles

Reason for Recall:
Lack of Assurance of Sterility: Product is not terminally sterialized and not tested per USP 71.

Recall Number:
D-1128-2019

Code Information:
Lot # 1808051, Exp. Date 01/01/22

Product Description:
Dr. Berne's MSM DROPS 15% Solution, Net Wt. 30ml/1.014 OZ, Distributed by: Dr. Berne's Whole Heallth Products, 400 Hillsboro Technology Drive, Deerfield BEach, FL 33441 SKU#182 UPC 00854582001036

Product Quantity:
500 30 mL bottles

Reason for Recall:
Lack of Assurance of Sterility: Product is not terminally sterialized and not tested per USP 71.

Recall Number:
D-1129-2019

Code Information:
Lot # 1808051, Exp. Date 01/01/22

Class II Drugs Event

Event ID:
82463

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
InvaGen Pharmaceuticals, Inc.
550 S Research Pl
Central Islip NY United States

Distribution Pattern:
Nationwide in the U.S.A.

Associated Products

Product Description:
Testosterone Cypionate Injection, USP, 2000 mg/10 mL (200 mg/mL), For intramuscular use only, 10 mL Vial, Multiple-Dose, Rx Only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc., 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323, NDC 69097-537-37.

Product Quantity:
75,968 vials

Reason for Recall:
Presence of Particulate Matter.

Recall Number:
D-1123-2019

Code Information:
Lot #: GH80159, GH80160, GH80161 Exp 01/2020; GH80489, GH80490, GH80502, GH80503, GH80504 Exp 03/2020; GH80557, GH80598, GH80601, GH80602 Exp 04/2020; GH80845, GH80846, GH80855, GH80856, GH80857, GH80877 Exp 06/2020; GH80903, GH80908, GH80931 Exp 07/2020; GH81047 Exp 08/2020.

Product Description:
Testosterone Cypionate Injection, USP, 200 mg/mL, For IM use only, 1 mL Vial, Single Dose, Rx Only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc., 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323, NDC 69097-537-31.

Product Quantity:
692,538 vials

Reason for Recall:
Presence of Particulate Matter.

Recall Number:
D-1124-2019

Code Information:
Lot #:GH80009, GH80010, GH80011 Exp 12/2019; GH80568, GH80575, GH80579, GH80580, GH80581, GH80582 Exp 4/2020; GH80646, GH80664, GH80665, GH80684, GH80699, GH80700, GH80701, GH80746, GH80761, GH80765, GH80777 Exp 05/2020; GH80801, GH80823, GH80828, GH80878 Exp 06/2020; GH80967, GH80968, GH81033, GH81034 Exp 07/2020; GH81042, GH81154 Exp 08/2020; GH81255, GH81256, GH81288, GH81289, GH81310 Exp 10/2020.

Product Description:
Testosterone Cypionate Injection, USP, 1000 mg/10 mL (100 mg/mL), For intramuscular use only, 10 mL Vial, Multiple-Dose, Rx Only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc., 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323, NDC 69097-536-37.

Product Quantity:
12,234 vials

Reason for Recall:
Presence of Particulate Matter.

Recall Number:
D-1125-2019

Code Information:
Lots #: GH80216 Exp 1/2020; GH80322, GH80323 Exp 2/2020; GH90072 Exp 12/2020.

Class II Drugs Event

Event ID:
82554

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/18/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy
Attn: Cleve Anderson 310 Bluff City Hwy
Bristol TN United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Acetylcysteine 10% Ophthalmic Eye Drop 2 mL droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy Bristol, TN.

Product Quantity:
10 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1137-2019

Code Information:
All Lots

Product Description:
Atropine 0.01% Eye Drops, 1 mL and 2 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1138-2019

Code Information:
All Lots

Product Description:
Amphotericin B 0.15% Eye Drops, 2 mL Droppers, Anderson Compounding Pharmacy 310 Bluff City Hwy Bristol, TN.

Product Quantity:
5 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1139-2019

Code Information:
All Lots

Product Description:
Vancomycin 125 mg/3mL Inhalation, 3 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1140-2019

Code Information:
All Lots

Product Description:
Dexamethasone 24 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy, 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
3 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1141-2019

Code Information:
All Lots

Product Description:
DMSO 50% 60 mL/Heparin 1 mL/ Sodium Bicarbonate 60 mL/ Solu-Cortef 100 mg, 41 mL syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1142-2019

Code Information:
All Lots

Product Description:
Estradiol Cypionate 10 mg/mL, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
35 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1143-2019

Code Information:
All Lots

Product Description:
Gentamicin 120 mg/250 mL 0.9% Sodium Chloride for Irrigation, 30 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
6 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1144-2019

Code Information:
All Lots

Product Description:
Gentamicin 250 mg/1000 mL Irrigation, 1000 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
4 bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1145-2019

Code Information:
All Lots

Product Description:
HCG 1,000 U/mL Injection, 30 mL, Vial Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1146-2019

Code Information:
All Lots

Product Description:
HCG 11,000 Units, 30 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
9 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1147-2019

Code Information:
All Lots

Product Description:
HCG 20 Day Injection, 2625 Units/4 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
217 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1148-2019

Code Information:
All Lots

Product Description:
HCG 23 Day, 2876 Units/4.6 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
31 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1149-2019

Code Information:
All Lots

Product Description:
HCG 30 Day, 3750 Units/6 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN 1-800-263-8890

Product Quantity:
57 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1150-2019

Code Information:
All Lots

Product Description:
HCG 20 Day Extra Strength, 3500 Units/4 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
99 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1151-2019

Code Information:
All Lots

Product Description:
HCG 20,000 units/vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1152-2019

Code Information:
All Lots

Product Description:
HCG 23 Day Injection Extra Strength, vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN 1-800-263-8890

Product Quantity:
14 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1153-2019

Code Information:
All Lots

Product Description:
HCG 4,100 Units/vial Injection, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1154-2019

Code Information:
All Lots

Product Description:
HCG 40 Day Injection Extra Strength, vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
2 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1155-2019

Code Information:
All Lots

Product Description:
Heparin 20,000 U/Lidocaine 2% 10 mL/Sodium Bicarbonate 8.4% 10 mL/Sterile Water 5 mL, 27 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1156-2019

Code Information:
All Lots

Product Description:
Heparin 10 mL/ Marcain 0.25% 20 mL/Sodium Bicarbonate 8.4%-40 mL/ Normal Saline 5 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1157-2019

Code Information:
All Lots

Product Description:
Heparin 10,000 U/Bupivacaine 0.5% 10 mL, Sodium Bicarbonate 8.4% 50 mL, 61 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1158-2019

Code Information:
All Lots

Product Description:
Heparin 10 mL/Marcain 0.25% 20 mL/Sodium Bicarbonate 8.4%-40 mL/per 70 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
12 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1159-2019

Code Information:
All Lots

Product Description:
Heparin 2 mL/Lidocaine 2%-10 mL/Sodium Bicarbonate 8.4%-5mL/ Sterile Water 10 mL, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
6 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1160-2019

Code Information:
All Lots

Product Description:
Methionine 15mg/Choline 100mg/ Inositol 50mg/ Methylcobalamin 1mg/ Lidocoaine 10 mg, benzyl alcohol/ water, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
276 vails

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1161-2019

Code Information:
All Lots

Product Description:
Methylcobalamin 1 mg/mL Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1162-2019

Code Information:
All Lots

Product Description:
Methylprednisolone 1% PF Ophthalmic, 3 mL Droppers, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1163-2019

Code Information:
All Lots

Product Description:
Morphine Sulfate 5 mg/3mL Inhalation, 3 mL Vials, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
60 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1164-2019

Code Information:
All Lots

Product Description:
Penicillin G 100,000/mL 10 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1165-2019

Code Information:
All Lots

Product Description:
Phenylephrine 1 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1166-2019

Code Information:
All Lots

Product Description:
Polyhexamethylene Biguanide 0.02% Ophthalmic Drops, 2 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1167-2019

Code Information:
All Lots

Product Description:
Prostaglandin 20 mcg/mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
23 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1168-2019

Code Information:
All Lots

Product Description:
Prostaglandin 40 mcg/mL, Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
6 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1169-2019

Code Information:
All Lots

Product Description:
Prostaglandin 60 mcg/mL, Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1170-2019

Code Information:
All Lots

Product Description:
Prostaglandin Quad-Mix 20:30:1:0.15 Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
40 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1171-2019

Code Information:
All Lots

Product Description:
Prostaglandin Quad with Atropine 10:30:1:0.15, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1172-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 20:30:1, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
58 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1173-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 50:30:1, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
31 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1174-2019

Code Information:
All Lots

Product Description:
Sermorelin 0.3 mg/0.5 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
22 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1175-2019

Code Information:
All Lots

Product Description:
Sermorelin 0.4 mg/0.5 mL, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
6 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1176-2019

Code Information:
All Lots

Product Description:
Serum Tears 20% Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
40 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1177-2019

Code Information:
All Lots

Product Description:
Serum Tears 30% Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
60 drop containers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1178-2019

Code Information:
All Lots

Product Description:
Streptomycin 24 mg/Dexamethasone 10 mg/mL Otic Injection, 1 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
10 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1179-2019

Code Information:
All Lots

Product Description:
Bacitracin 3000U/30 mL Irrigation, 30 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
2 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1180-2019

Code Information:
All Lots

Product Description:
Testosterone Cypionate 250 mg/mL Sterile Injection, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1181-2019

Code Information:
All Lots

Product Description:
Vitamin D3 200,000 IU/mL Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:
4 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1182-2019

Code Information:
All Lots

Product Description:
Methylcobalamin 3000 mcg/mL Injection Solution, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1183-2019

Code Information:
All Lots

Product Description:
Serum Tears 50% Ophthalmic Drops, 1 mL Dropper, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1184-2019

Code Information:
All Lots

Product Description:
Interferon 1 Million IU/mL Eye Drops, 1 mL Droptainer, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1185-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 60:30:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1186-2019

Code Information:
All Lots

Product Description:
Neomycin 40 mg/Polymixin B 200,000 Bladder Irrigation Solution, 1000 mL bottle, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1187-2019

Code Information:
All Lots

Product Description:
Lidocaine 1%/Dextrose 12.5% (PF) Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1188-2019

Code Information:
All Lots

Product Description:
EDTA 1% Sterile Injection (Preservative Free), Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1189-2019

Code Information:
All Lots

Product Description:
Sodium Bicarbonate 8.4% Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1190-2019

Code Information:
All Lots

Product Description:
Heparin 20,000U/Marcaine 0.25%, 10 mL, Sodium Bicarbonate 8.4% 48 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1191-2019

Code Information:
All Lots

Product Description:
Gentamicin 160 mg/1000 mL Sterile Water for Irrigation,1000 mL Bottle, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1192-2019

Code Information:
All Lots

Product Description:
Gentamicin 240 mg/500 mL Sterile Water for Irrigation,60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1193-2019

Code Information:
All Lots

Product Description:
Heparin 10 mL/Marcaine 0.25% 20 mL/Sodium Bicarbonate 40 mL/Normal Saline 5 mL per 75 mL, 60 mL Syringe, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1194-2019

Code Information:
All Lots

Product Description:
Estrone 5mg/mL Oil Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1195-2019

Code Information:
All Lots

Product Description:
HCG 11,00Units/B 12 11,000 mcg Injection, 30 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1196-2019

Code Information:
All Lots

Product Description:
Papaverine 30 mg/Phentolamine 0.5 mg/mL, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1197-2019

Code Information:
All Lots

Product Description:
Papaverine 30 mg/mL Injection, 10 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1198-2019

Code Information:
All Lots

Product Description:
Phenol 10% Injection, 5 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1199-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 5:15:0.5 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1200-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 2.5:7.5:0.25 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1201-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 8.33:22.5:0.833 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1202-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 20:25:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1203-2019

Code Information:
All Lots

Product Description:
Prostaglandin Tri-Mix 30:30:1 Injection, 2 mL Vial, Anderson Compounding Pharmacy 310 Bluff City Hwy, Bristol, TN.

Product Quantity:

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1204-2019

Code Information:
All Lots

Class II Drugs Event

Event ID:
82617

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/15/2019

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:
Product was distributed to major distributors and retailers who may have further distribute the product throughout the United States.

Associated Products

Product Description:
Divalproex Sodium Extended-Release Tablets, USP, a) 100-count bottle (NDC 55111-0533-01), b) 500-count bottle (NDC 55111-0533-05), Rx only, Mfd. By: Dr. Reddy's Laboratories Limited, Bachupally, - 500 090 INDIA

Product Quantity:
33,958 bottles

Reason for Recall:
cGMP deviations: Product was exposed above 50% relative humidity levels during packaging operations.

Recall Number:
D-1133-2019

Code Information:
Lot #: a) C802629, Exp. 03/2020; C805680, Exp. 07/2020, C808821,Exp. 10/2020; b) C806561, Exp. 10/2020

Class III Drugs Event

Event ID:
82452

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Estee Lauder Inc
767 5th Ave Fl 47th
New York NY United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Repairwear Laser Focus Line Smoothing Cream Broad Spectrum SPF 15, packaged in a light green folding carton containing a 50 mL silver jar with a silver cap, Clinique Laboratories, Dist. New York, NY 10022

Product Quantity:
14490 jars

Reason for Recall:
Defective container: Ineffective seal between the cap and jar of the affected product.

Recall Number:
D-1132-2019

Code Information:
Lot #: A68

Not Yet Classified Drugs Event

Event ID:
82618

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Johnson Matthey Inc.
2003 Nolte Dr
West Deptford NJ United States

Distribution Pattern:
Product was distributed to one manufacturer in Morgantown, WV who may have manufactured the product into finished product and further distribute to the retail level Nationwide in the USA.

Associated Products

Product Description:
Remifentanil HCl active pharmaceutical ingredient (API) for manufacturing, processing or repackaging, 416.95 g glass container, Rx ONLY, Johnson Matthey Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, NJ 08066-1742.

Product Quantity:
416.95 g glass container

Reason for Recall:
Failed Impurities/Degradation Specifications: Unknown impurity above specification limits.

Recall Number:

Code Information:
Lot #: B1319-170101