Enforcement Report - Week of May 8, 2019

Class II Drugs Event

Event ID:
82615

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/08/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/30/2019

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

Recalling Firm:
Customceutical Compounding
4611 E Shea Blvd Bldg 3 Ste 180
Phoenix AZ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
BPlex (METHYLCOBALAMIN 1000 MCG/ML PYRIDOXAL 5 PHOSPHATE 20MG/ML DEXPANTHENOL 250MG/ML), 10 ML MULTIDOSE VIAL MDV INJ COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
32 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1253-2019

Code Information:
Lot #: 02082019@9, Exp 5/19/19

Product Description:
BPlex (METHYLCOBALAMIN 1000 MCG/ML PYRIDOXAL 5 PHOSPHATE 20MG/ML DEXPANTHENOL 250MG/ML), 10 ML MULTIDOSE VIAL MDV INJ COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
19 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1254-2019

Code Information:
Lot #: 03122019@31, Exp 6/10/19

Product Description:
Glutathione 200mg/mL inj. a) 10 ML and b) 12 ML MULTIDOSE VIAL MDV Compounded. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
4 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1255-2019

Code Information:
Lot #: 02132019@25, Exp 5/14/19

Product Description:
HCG (CHORIONIC GONADOTROPIN 1000 IU/ML PEP 25 mg/mL) inj 5 mL multidose vial compounded. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
12 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1256-2019

Code Information:
Lot #: 03132019@23, Exp 5/12/19

Product Description:
Lipoplex (METHIONINE 25 MG/ML INOSITOL 50 MG/ML CHOLINE CHLORIDE 50 MG/ML HYDROXOCOBALAMIN 500 MC/ML DEXPANTHENOL 50 MG/ML PYRIDOXINE HCL 50 MG/ML), 10 ML MULTIDOSE VIAL INJ COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
16 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1257-2019

Code Information:
Lot #: 02212019@13, Exp 5/22/19

Product Description:
Test D (TESTOSTERONE CYPIONATE 200MG/ML VITAMIN D3 5,000IU/ML), 5 ML MULTIDOSE VIAL COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
8 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1258-2019

Code Information:
Lot #: 01232019@25, Exp 4/23/19

Product Description:
Test D (TESTOSTERONE CYPIONATE 200MG/ML VITAMIN D3 5,000IU/ML), 5 ML MULTIDOSE VIAL COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
2 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1259-2019

Code Information:
Lot #: 03132019@28, Exp 6/11/19

Product Description:
Test PROCYP (TESTOSTERONE CYPIONATE 200MG/ML TESTOSTERONE PROPIONATE 20MG/ML), 5 ML MULTIDOSE VIAL INJ

COMPOUNDED. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
5 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1260-2019

Code Information:
Lot #: 03112019@10, Exp 6/19/19

Product Description:
Trimix HIGH (Papaverine HCl 30 mg/mL Phentolamine Mesylate 2 mg/mL Alprostadil 20 mcg/mL), 2 mL multidose vial MDV Inj. Compounded. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:
3 vials

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1261-2019

Code Information:
Lot #: 02182019@27, Exp 8/02/19

Product Description:
TriMix MEDIUM (Papaverine HCL 21 mg/mL Phentolamine Mesylate 0.7 mg/mL Alprostadil 7 mcg/mL), 2 mL multidose MDV Inj. Compounded. Customceutical Compounding 4611 E. Shea Blvd. Bldg 3 180, Phoenix, AZ 85028 Ph. 480 516 0272

Product Quantity:

Reason for Recall:
Lack of assurance of sterility for injectables and solutions intended to be sterile.

Recall Number:
D-1262-2019

Code Information:
Lot #: 02182019@22, Exp 8/02/19

Class II Drugs Event

Event ID:
82661

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/18/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/01/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 25 mg, a) 90-count (NDC: 13668-113-90), b)1000-count (NDC: 13668-113-10) per bottle, Rx only, Manufactured

by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
28,464 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1264-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot BDK1C003, exp 07/31/2019; [1000-count bottle] Lot BDK1C002, exp 07/31/2019; Lots 4DU1D004, 4DU1D005, 4DU1D006, exp 12/31/2019

Product Description:
Losartan Potassium Tablets, USP, 50 mg, a) 90-count (NDC: 13668-409-90), b)1000-count (NDC: 13668-409-10) per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
164,424 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1265-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lots 4DU2D005, 4DU2D006, exp 12/31/2019; Lots 4DU2D026, 4DU2D027, 4DU2D029, exp 3/31/2020; Lot 4DU2E007, exp 12/31/2020; [1000-count bottle] Lot 4DU2D017, exp 2/29/2020, Lots 4DU2D025, 4DU2D028, exp 3/31/2020; Lots 4DU2D040, 4DU2D041, 4DU2D042, 4DU2D045, 4DU2D046, 4DU2D047, 4DU2D048, exp 8/31/2020; Lot BDK2E001, exp 12/31/2020; Lots 4DU2E042, 4DU2E044, exp 2/28/2021; Lots BDK2E012, BDK2E013, exp 8/31/2021

Product Description:
Losartan Potassium Tablets, USP, 100 mg, a) 90-count (NDC: 13668-115-90), b)1000-count (NDC: 13668-115-10) per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
65,184 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1266-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot 4DU3E016, exp 01/31/2021; [1000-count bottle] Lot 4DU3C012, exp 7/31/2019; Lots 4DU3C015, 4DU3C016, 4DU3C017, exp 8/31/2019; Lot 4DU3C031, exp 9/30/2019; Lots 4DU3D007, 4DU3D008, exp 1/31/2020; Lot 4DU3E017, exp 1/31/2021; Lot 4DU3E019, exp 2/28/2021

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP, 50mg/12.5mg, a) 30-count (NDC: 13668-116-30), b) 90-count (NDC: 13668-116-90), c) 1000-count (NDC: 13668-116-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
331,764 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1267-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BP02C051, exp 10/31/2019; Lot BP02D005, exp 12/31/2019; Lot BEF7D047, exp 11/30/2020; [90-count bottle] Lot BP02C050, exp 10/31/2019; Lots BP02D006, BP02D007, exp 12/31/2019; Lot BP02D012, exp 1/31/2020; Lot BEF7D003, exp

3/31/2020; Lots BEF7D026, BEF7D027, BEF7D028, exp 8/31/2020; Lots BEF7D045, BEF7D046, exp 11/30/2020; Lot BEF7E005, exp 1/31/2021; [1000-count bottle] Lots BP02C051, BP02C052, exp 10/31/2019; Lot BEF7D005, exp 3/31/2020; Lots BEF7D029, BEF7D030, exp 8/31/2020; Lot BEF7D048, exp 11/30/2020; Lots BEF7E001, BEF7E002, BEF7E003, BEF7E004, exp 12/31/2020

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP, 100mg/12.5mg, a) 90-count (NDC: 13668-117-90), b) 1000-count (NDC: 13668-117-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
54,084 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1268-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot BX35D024, exp 1/31/2020; BEF8D060, BEF8D061, BEF8D062, BEF8D063, BEF8D064, exp 11/30/2020; [1000-count bottle] Lot BEF8D059, exp 11/30/2020; Lots BEF8E004, BEF8E005, exp 1/31/2021

Product Description:
Losartan Potassium and Hydrochlorothiazide Tablets, USP, 100mg/25mg, a) 30-count (NDC: 13668-118-30) b) 90-count (NDC: 13668-118-90), c) 1000-count (NDC: 13668-118-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India

Product Quantity:
239,016 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 9.82 parts per million.

Recall Number:
D-1269-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BEF6D054, exp 8/31/2020; [90-count bottle] Lot BP04C092, exp 10/31/2019; Lots BP04D012, BP04D013, exp 12/31/2019; Lots BEF6D012, BEF6D013, exp 3/31/2020; Lots BEF6D060, BEF6D061, BEF6D063, exp 9/30/2020; Lots BEF6D076, BEF6D077, BEF6D078, BEF6D079, exp 10/31/2020; Lots BEF6D100, BEF6D101, BEF6D102, exp 11/30/2020; Lots BEF6E001, BEF6E002, BEF6E003, BEF6E004, BEF6E008, BEF6E009, BEF6E010, BEF6E011, BEF6E012, exp 12/31/2020

Class II Drugs Event

Event ID:
82676

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/19/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/07/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pacifico National, Inc. dba AmEx Pharmacy
1515 Elizabeth St Ste J
Melbourne FL United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
BEVACIZUMAB 1.25 mg/0.05 mL 31G MJ syringe Intravitreal Injection. This biologic product was repackaged by AmEx Pharmacy 1515 Elizabeth St. Suite J Melbourne, FL 32901 Lot:190212AB BUD:5/13/2019, Repackaged on 2/12/2019

Product Quantity:
249 syringes

Reason for Recall:
Defective Delivery System: difficult to express

Recall Number:
D-1271-2019

Code Information:
Lot: 190212AB BUD: 5/13/2019

Class II Drugs Event

Event ID:
82706

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/28/2019

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:
Losartan Potassium Tablets USP 50 mg 50 tablets (5x10) Unit Dose Rx Only NDC 50268-517-15 Manufactured for: AvKARE Inc. Pulaski, TN 38478

Product Quantity:
1438 cartons (71,900 tablets)

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 0.96 parts per million.

Recall Number:
D-1249-2019

Code Information:
Lot: 20121 Exp. 6/30/2019

Product Description:
Losartan Potassium Tablets USP 25 mg 50 tablets (5x10) Unit Dose Rx Only NDC 50268-516-15 Manufactured for: AvKARE Inc. Pulaski, TN 38478

Product Quantity:
846 cartons (42,300 tablets)

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level of 0.96 parts per million.

Recall Number:
D-1250-2019

Code Information:
Lot: 19554 Exp. 4/30/2019

Class II Drugs Event

Event ID:
82710

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/01/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Legacy Pharmaceutical Packaging LLC
13333 Lakefront Dr
Earth City MO United States

Distribution Pattern:
TN, AZ

Associated Products

Product Description:
Losartan Potassium Tablets, USP, 50 mg, 30 tablet bottles, Rx Only, Distributed by: The Kroger Co, Cincinnati, OH 45202, Manufactured for: Torrent Pharma Inc., 150 Allen Road, Suite 102, Basking Ridge, NJ 07920, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045 NDC 68645-494-54

Product Quantity:
60,012 bottles

Reason for Recall:
CGMP Deviations: Detection of trace amounts of N-Methylnitrosobutyric acid (NMBA) impurity found in the Active Pharmaceutical Ingredient (API)

Recall Number:
D-1263-2019

Code Information:
Lot 181598; 02/2021

Class II Drugs Event

Event ID:
82718

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/26/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/29/2019

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

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

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
HYDROmorphone 20 mg/100 mL Injectable Solution, Hydromorphone HCl 20 mg 0.9% Sodium Chloride 100 mL, Sterile single use bag, Compounded Drug, Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404, NDC: 42852-221-10

Product Quantity:
560 bags

Reason for Recall:
Sub-potency

Recall Number:
D-1251-2019

Code Information:
Lot: 01/14/19 0215 22110P Exp. 04/29/2019

Not Yet Classified Drugs Event

Event ID:
82593

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/08/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
GlipiZIDE Extended-release Tablets, 2.5 mg, 30 Tablets (3 x 10), Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC: 68084-295-21

Product Quantity:
2,203 cartons (cartons of 30 individual unit doses)

Reason for Recall:
Failed Dissolution Specifications: dissolution failure at time zero of the repackaged lot. Drug release results were slightly above specification at time zero.

Recall Number:

Code Information:
Lot # 181288, EXP 5/31/2020

Not Yet Classified Drugs Event

Event ID:
82660

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Worldmeds LLC

4441 Springdale Rd
Louisville KY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Revonto (dantrolene sodium for injection), 20 mg/vial, For treatment of malignant hyperthermia, For Intravenous Use Only, Rx Only, Made in Italy, Dist. by: US WorldMeds, LLC, Louisville, KY 40241, NDC: 27505-003-67

Product Quantity:
6456 vials

Reason for Recall:
Presence of Precipitate: Appearance is Out of Specification for the reconstituted solution during 24-month stability time point analysis.

Recall Number:

Code Information:
Lot: 17REV01, Exp. 12/2019

Not Yet Classified Drugs Event

Event ID:
82709

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advantice Health
7 E Frederick Pl Ste 100
Cedar Knolls NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Dermoplast Anesthetic PAIN & ITCH (benzocaine and menthol) SPRAY canisters, 20%, 0.5%, Net WT 2.75 oz (78g); Distributed by Moberg Pharma North America LLC, Cedar Knolls, NJ 07927; UPC 8 51409 00722 6

Product Quantity:
111,492 canisters

Reason for Recall:
Labeling: Not Elsewhere Classified: canisters incorrectly state the net weight is 2.75 oz. rather than the correct net weight of 2.0 oz.

Recall Number:

Code Information:
Lot #: 14049A, Exp 12/21