Enforcement Report - Week of April 17, 2019

Class I Drugs Event

Event ID:
82336

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/05/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
USA LESS Inc.
1864 Sterling Pl
Brooklyn NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
LEOPARD Miracle Honey packaged in a wooden box, UPC 8 699415 910534, containing 12 sachets 180Gr / 6.36 Oz, each 1 Sachet 15 gr / 0.53 Oz is labeled as LEOPARD Miracle of Honey, UPC 8 699415 912859, Manufactured in Turkey, www leopardhoneytr.com.

Product Quantity:
83 boxes

Reason for Recall:
Marketed Without An Approved NDA/ANDA: product tainted with undeclared sildenafil, an FDA approved drug for the treatment of male erectile dysfunction. The presence of sildenafil in Leopard Miracle Honey renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Recall Number:
D-1135-2019

Code Information:
All lots

Class II Drugs Event

Event ID:
82106

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/09/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
McDaniel Life-Line LLC
Hc 1 Box 2b
Felt OK United States

Distribution Pattern:
Nationwide, Italy, Australia, Canada, Poland

Associated Products

Product Description:
Indian Herb Paste (a dietary supplement) Ingredients: Galangal, Indian Paint, Yellow Dock & Licorice in an alloy of Life-Line tm and Zinc Chloride in 6 dram vials, McDaniel Life-Line LLC, Dimmitt, TX

Product Quantity:
150 vials

Reason for Recall:
Unapproved new drug

Recall Number:
D-1111-2019

Code Information:
All lots within expiry

Product Description:
Life-Line tm Catalytic Activated Energy Water, 1 gallon container, McDaniel Life-Line LLC 1775 US Hwy 385 806-647-1741 Dimmitt, TX 79027

Product Quantity:
Unknown

Reason for Recall:
Unapproved new drug

Recall Number:
D-1112-2019

Code Information:
All lots within expiry.

Class II Drugs Event

Event ID:
82278

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/21/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/09/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Health Solutions Pharmacy Center Inc dba Professional Compounding Pharmacy
996 Nw Circle Blvd Ste 105
Corvallis OR United States

Distribution Pattern:
Dispensed in Oregon

Associated Products

Product Description:
SODIUM CHLORIDE PRES-FREE 5% OPHTH STERILE* SOLUTION. 20ml eye drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
1 prescription 20ml solution

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1086-2019

Code Information:
Lot: 12022019@30, distributed between 09-01-2018 to 02-20-2019.

Product Description:
DEXAMETHASONE (NAPO4) 0.1% OPHTH* PRES-FREE SOLUTION, 10ml, Eye Drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
12 prescriptions

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1087-2019

Code Information:
Lots: 23012019@48, 24012019@2, 24012019@36, 28012019@35, 29012019@13, 05022019@5, 11022019@13, 12022019@20, 19022019@1, 19022019@6, 19022019@57, 19022019@61, All lots within expiry distributed between 09-01-2018 to 02-20-2019.

Product Description:
ACETYL-L-CYSTEINE 10% P.F. OPHTH SOLUTION, 10ml, eye drops, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
6 prescriptions 10ml dropper bottle

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1088-2019

Code Information:
Lots: 17012019@13, 30012019@36, 01022019@4, 14022019@1, 19022019@18, 19022019@60, distributed between 09-01-2018 to 02-20-2019.

Product Description:
HYDROXYPROGESTERONE CAPROATE 250 MG/ML OIL* INJECTABLE, (a) 10ml (b) 9ml injectable, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
4 prescriptions 9 & 10ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1089-2019

Code Information:
Lots: (a) 01112018@19, 04012019@52, 14022019@23, (b) 14012019@36, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 22-0.8 MG-8 MCG/ML* INJECTABLE, (a) 5ml (b) 10ml, (c) 6ml, penile injection, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
64 prescriptions 5, 10, 6 mL injections

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1090-2019

Code Information:
Lot: (a) 18092018@52, 01102018@9, 05102018@36, 08102018@11, 102018@9, 01102018@9, 01102018@9, 03102018@27, 12102018@18, 01102018@9, 12102018@18, 12102018@18, 17102018@15, 12102018@18, 2102018@18, 22102018@31, 30102018@22, 29102018@9,29102018@9 29102018@9, 29102018@9, 12102018@18, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 21112018@38, 11122018@7, 11122018@7, 28122018@11, 28122018@11, 28122018@11, 03012019@17, 03012019@17, 03012019@17, 08012019@21, 08012019@21,28082018@16 28082018@16, 28082018@16, 14092018@28, 14092018@28, 4092018@28, 14092018@28, 18092018@52, 18092018@52, 8092018@52, 18092018@52, 18092018@52, (b) 29102018@9, 03012019@17,14092018@28, (c)

11012019@64, 11012019@64, 11012019@64, 05022019@27, 5022019@27, 06022019@6, 06022019@6, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PGE1 40 MCG/ML* INJECTABLE, (2) 5ml (b) 10ml, (c) 6ml (d) 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
5 prescriptions 5,10, 6, 9 ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1091-2019

Code Information:
Lot:(a) 10102018@30, (b) 31102018@33,05112018@1, (c)15012019@8, (d) 30012019@33, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE 30-1 MG/ML* INJECTABLE, (a)10ml (b) 9ml, penile injection, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
3 prescriptions 10, 9, ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1092-2019

Code Information:
Lot:(a) 08102018@11, 27122018@33, (b) 30012019@43, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 30-1 MG-10 MCG/ML* INJECTABLE, (a) 5ml, (b) 6ml, (c) 9ml (d) 10ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
13 prescription 5, 6, 9, 10 ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1093-2019

Code Information:
Lot: (a) 03102018@27, 07112018@18, 08112018@11, 16112018@15, 28112018@7, 14122018@37,16112018@41, 03012019@9, (b) 2012019@32, 23012019@59, (c)07022019@19, 07022019@1, (d)19122018@25, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 12-1MG-10MCG/ML INJECTABLE, (a) 10ml, (b) 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
9 prescriptions 10, 9ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1094-2019

Code Information:
Lot (a)17102018@15,14112018@3, 04122018@21, 14122018@15, 7122018@11, 28122018@69, 20092018@2, (b) 21012019@37, 22012019@31, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 17.16-0.57MG-19.45MCG/ML* INJECTABLE, 5ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
2 prescription 5ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1095-2019

Code Information:
Lot 30102018@22, 15112018@5, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 23-0.96MG-19.2MCG/ML INJECTABLE, (a) 5ml, (b) 6.5ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330

Product Quantity:
2 prescription 5, 6.5 ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1096-2019

Code Information:
Lot: (a) 22102018@31, (b) 09112018@33, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 30-1.6 MG-16 MCG/ML* INJECTABLE, (a) 5ml, (b) 10ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
3 prescription 5, 10 ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1097-2019

Code Information:
Lot: 05102018@36,27112018@49, (b) 28112018@54, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PGE1-LIDOCAINE 40 MCG-1% /ML* INJECTABLE, (a) 10 ml (b) 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
25 prescriptions 10, 9, ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1098-2019

Code Information:
Lot:(a) 26092018@22, 26092018@22, 09102018@47, 15102018@33, 15102018@33, 09102018@47, 15102018@33, 09102018@47, 29112018@4, 10122018@14, 29112018@4, 29112018@4, 19122018@20, 21122018@29, 21122018@29, 27122018@20, (b) 16012019@59, 18012019@17, 21012019@49, 21012019@49, 22012019@24, 22012019@24, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE 15-0.5MGMG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription 9ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1099-2019

Code Information:
Lot:15012019@10, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE 30-0.5 MG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 9ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1100-2019

Code Information:
Lot:19022019@21, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 30-2 MG-30 MCG/ML* INJECTABLE, 5ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 5ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1101-2019

Code Information:
Lot:15112018@40 , distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 15-0.5MG-10MCG/ML INJECTABLE, 9ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 9ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1102-2019

Code Information:
Lot:17012019@27, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 16.6-0.55 MG-11.1 MCG/ML* INJECTABLE, 10 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
2 pre4scriptions 10 ml injections

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1103-2019

Code Information:
Lot:09112018@55, 09012019@37, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 17.64-0.58MG-5.88MCG/ML* INJECTABLE, 9 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription 9ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1104-2019

Code Information:
Lot:17012019@18, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 22.5-0.8MG-8.3MCG/ML INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
2 prescriptions, 5ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1105-2019

Code Information:
Lot:26112018@68, 13122018@12, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 9-1 MG-10 MCG/ML* INJECTABLE, 18 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 18ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1106-2019

Code Information:
Lot:12022019@23, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 30-1 MG-20 MCG/ML* INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
3 prescriptions, 5ml injectable

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1107-2019

Code Information:
Lot:20092018@41, 25092018@7, 27092018@3, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 15-0.25MG-6MCG/ML INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 5ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1108-2019

Code Information:
Lot:06092018@57, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 17.44-0.58MG-5.8MCG/ML* INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 5ml

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1109-2019

Code Information:
Lot:19092018@1, distributed between 09-01-2018 to 02-20-2019.

Product Description:
PAPAVERINE-PHENTOLAMINE-PGE1 17.44-0.64MG-5.8MCG/ML* INJECTABLE, 5 ml, Professional Compounding Pharmacy, 996 NW Circle Blvd. #105 Corvallis, OR 97330 .

Product Quantity:
1 prescription, 5ml injection

Reason for Recall:
Lack of Processing Controls: Insanitary conditions observed during compounding of sterile drugs during recent FDA Inspection.

Recall Number:
D-1110-2019

Code Information:
Lot:13092018@44, distributed between 09-01-2018 to 02-20-2019.

Class II Drugs Event

Event ID:
82396

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/19/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/09/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LUPIN SOMERSET
400 Campus Dr
Somerset NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Gavilyte-N, PEG-3350, Sodium chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution, Rx only, Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873 Manufactured for Lupin Pharmaceuticals, Inc. Baltimore, MD NDC 43386-050-19 UPC 343386050192 a) Lemon Flavor Pack net wt. 2 g UPC 343386200023 b) Orange Flavor Pack net wt. 2 g UPC 343386202027 c) Cherry Flavor Pack net wt. 2 g UPC 3433862034

Product Quantity:
76422 bottles

Reason for Recall:
Labeling Not Elsewhere Classified; orange and cherry flavor packets incorrect list "natural lemon flavor" as an ingredient

Recall Number:
D-1113-2019

Code Information:
Lot #: a) S800021, Exp 30-Nov-20; b) S800175, Exp 31-Dec-20; c) S 800401, Exp 28-Feb-21; S800426, Exp 31-Mar-21; S800920, Exp 31-Aug-21.

Class II Drugs Event

Event ID:
82461

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Pravastatin Sodium Tablets USP, 20 mg, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma zone SEZ, Pithampur, Dist-Dhar, Madhya Pradesh 454 775, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430. NDC 68462-196-05

Product Quantity:
2076 500-count Bottles

Reason for Recall:
Presence Of Foreign Tablet: in a bottle of Pravastatin Sodium Tablets 20 mg.

Recall Number:
D-1120-2019

Code Information:
Lot 17181491 Exp. Aug. 2021

Class II Drugs Event

Event ID:
82532

Product Type:
Drugs

Status:
Terminated

Date Terminated:
04/11/2019

Recall Initiation Date:
03/14/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to one sole customer, Miami, FL.

Associated Products

Product Description:
Losartan 50mg Tablet, 30 count each blister card.

Product Quantity:
33 blister cards of 30 = 990 tablets

Reason for Recall:
CGMP Deviations; Detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) - N-Methylnitrosobutyric acid (NMBA).

Recall Number:
D-1081-2019

Code Information:
70518-0588-01, Lot #: J0328416-101518, Exp. Date: 10/2019

Class II Drugs Event

Event ID:
82538

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lohxa LLC
600 Main St Ste 110
Worcester MA United States

Distribution Pattern:
MA, NY and WY

Associated Products

Product Description:
Bismuth Subsalicylate Oral Suspension 262mg/15mL, unit dose cups, OTC, Rpkg. By.: Lohxa Worcester, MA, NDC 70166-059-01

Product Quantity:
5 boxes - 250 unit dose cups.

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date - the label contains an incorrect Exp Date.

Recall Number:
D-1130-2019

Code Information:
Lot#: M030042P, Exp. 01/2020

Product Description:
Phenobarbital Oral Solution, USP 20 mg/5mL, unit dose cup, Rx Only, Rpkg. By.Lohxa Worcester, MA 01608 NDC 70166-536-02

Product Quantity:
46 boxes - 1380 unit dose cups

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date - the label contains an incorrect Exp Date.

Recall Number:
D-1131-2019

Code Information:
Lot# M12031, Exp. 12/2019; T01241 Exp. 02/2020

Class II Drugs Event

Event ID:
82574

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/07/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
H J Harkins Company Inc dba Pharma Pac
1400 W Grand Ave Ste F
Grover Beach CA United States

Distribution Pattern:
Product was distributed to a physician's office in California.

Associated Products

Product Description:
Losartan Potassium 100 mg Tablets # 30 Losartan potassium tablets USP, 100 mg are white to off white, film coated, tear drop shaped tablets, debossed with "H" on one side and "145" on the other side.

Product Quantity:
300 tablets

Reason for Recall:
CGMP Deviations:Traces amounts of N-Nitroso N-Methyl 4- amino butyric acid (NMBA) impurity found in Active Pharmaceutical Ingredient (API).

Recall Number:
D-1083-2019

Code Information:
Pharma Pac NDC: 76519-1033-03, Pharma Pac Lot # LTO00EW, Exp. 11/19, MFG NDC 31722-0702-30, MFG Lot # LOP17087, Exp. 11/2019.

Class II Drugs Event

Event ID:
82585

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/10/2019

Initial Firm Notification of Consignee or Public:
Letter

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. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:
133,992 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-1114-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lots 4DU1E005, 4DU1E006, 4DU1E008, exp 1/31/2021; Lots 4DU1E007, exp 1/31/2021

Product Description:
LOSARTAN POTASSIUM TABLETS, USP, 50 mg, a) 30-count (NDC: 13668-409-30), b) 90-count (NDC: 13668-409-90), c) 1000-count (NDC: 13668-409-10), per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:
476,340 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-1115-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot 4DU2D077, exp 10/31/2020; [90-count bottle] Lot 4DU2D087, exp 10/31/2020; Lots 4DU2E023, 4DU2E024, 4DU2E026, 4DU2E027, 4DU2E028, 4DU2E029, 4DU2E020, exp 1/31/2021; Lots 4O50E007, 4O50E008, exp 8/31/2021; [1000 count bottle] Lots 4DU2D067, 4DU2D069, 4DU2D063, 4DU2D064, 4DU2D065, 4DU2D066, exp 9/30/2020; Lots 4DU2D084, 4DU2D085, 4DU2D083, 4DU2D082, 4DU2D072, 4DU2D077, 4DU2D078, 4DU2D079, 4DU2D081, 4DU2D080, 4DU2D070, 4DU2D073, 4DU2D074, 4DU2D075, 4DU2D086, 4DU2D088, 4DU2D089, exp 10/31/2020; Lots 4DU2E019, 4DU2E021, 4DU2E022, 4DU2E025, exp 1/31/2021; Lots 4DU2E032, 4DU2E033, 4DU2E034, 4DU2E035, 4DU2E036, 4DU2E037, 4DU2E038, 4DU2E039, 4DU2E041, exp 2/28/2021; Lots 4DU2E103, 4DU2E101, 4DU2E102, exp 6/30/2021

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. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:
121,668 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-1116-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lots 4DU3E014, 4DU3E015, exp 1/31/2021; Lot 4DU3E065, exp 7/31/2021; [1000-count bottle] Lot 4DU3D018, exp 11/30/2020; Lots 4DU3E062, 4DU3E063, exp 6/30/2021

Product Description:
Losartan Potassium / 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. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:

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-1117-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BEF7D017,exp 6/30/2020 [90-count bottle] Lots BEF7D010, BEF7D011, exp 4/30/2020; Lot BEF7D018, exp 6/30/2020; Lot BEF7D009, exp 4/30/2020; Lots 4P02E002, 4P02E003, 4P02E004, exp 1/31/2021; [1000-count bottle] Lots BEF7D008, BEF7D012, BEF7D013, exp 4/30/2020; Lot BEF7D022, exp 8/31/2020; Lot BEF7D049, exp 11/30/2020; Lots 4P02E005, 4P02E006, exp 1/31/2021

Product Description:
Losartan Potassium / Hydrochlorothiazide Tablets, USP 100mg/12.5mg, a) 30-count (NDC: 13668-117-30), b) 90-count (NDC: 13668-117-90) per bottle , Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana India. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:
172,296 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-1118-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BEF8D058,exp 11/30/2020 [90-count bottle] Lots BEF8D009, BEF8D010, BEF8D011, BEF8D012, BEF8D013, BEF8D007, BEF8D008, exp 3/31/2020; Lots BEF8D023, BEF8D024, BEF8D025, BEF8D020, BEF8D021, BEF8D022, exp 4/30/2020; Lots BEF8D054, BEF8D055, BEF8D056, exp 10/31/2020; Lots BEF8D057, exp 11/30/2020

Product Description:
Losartan Potassium / 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. For: Torrent Pharma, Inc, 150 Allen Road, Suite 102, Basking Ridge, NJ

Product Quantity:
173,760 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-1119-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BEF6D038, exp 4/30/2020; [90-count bottle] Lots BEF6D030, BEF6D031, exp 4/30/2020; Lots BEF6D047, BEF6D048, BEF6D049, BEF6D050, BEF6D051, exp 7/31/2020; Lots BEF6D082, BEF6D083, BEF6D084, BEF6D085, BEF6D086, BEF6D087, exp 10/31/2020; Lots 4P04E003, 4P04E004, 4P04E005, 4P04E006, exp 1/31/2021; [1000-count bottle] 4P04E007, 4P04E008, 4P04E009, exp 1/31/2021

Class III Drugs Event

Event ID:
82483

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/22/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/05/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Auro Pharmacies Inc. DBA Central Drugs
511 S Harbor Blvd Ste F
La Habra CA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Biotin 10 mg/mL Injection, 30 mL vial, Rx only, 511 S. Harbor Blvd., Building. F, La Habra, CA 90631, 562-352-9630.

Product Quantity:
167 vials

Reason for Recall:
Failed pH Specification: product does not meet pH label claim.

Recall Number:
D-1082-2019

Code Information:
Lot 190205@1, expiry 08/4/19

Class III Drugs Event

Event ID:
82504

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/29/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
X-Gen Pharmaceuticals Inc.
300 Daniel Zenker Dr
Horseheads NY United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Clonidine HCL Injection, 1000 mcg/10mL (100 mcg/mL), 10 ML Single Dose Vial, Rx only, Manufactured for: X-Gen Pharmaceuticals, Big Flats, NY 14814, NDC 39822-2000-1.

Product Quantity:
24,966 vials

Reason for Recall:
Labeling: Label Error on Declared Strength: Side carton panel incorrectly lists the concentration as "500 mcg Clonidine Hydrochloride" rather than the correct concentration of "100 mcg Clonidine Hydrochloride" per mL.

Recall Number:
D-1084-2019

Code Information:
Lots #: PMXA1917, Exp 09/2020; PMXA1937, PMXA1938, Exp 11/2020;

Not Yet Classified Drugs Event

Event ID:
82496

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Product is being held at a distributor site in Mexico, Asheboro, NC, Charlotte, NC and Santa Teresa, NM and not further distributed in the U.S. Market.

Associated Products

Product Description:
Lidocaine HCl Injection, USP 1 % 50 mg/5 mL (10 mg/mL), 5mL vial, Rx only, Mrd. in India for: AuroMedics Pharna LLC. E Windsor, NJ 08520 NDC 55150-162-05

Product Quantity:
88600 vials

Reason for Recall:
Presence of Particulate Matter: One vial was found to contain a hair.

Recall Number:

Code Information:
Lot #: CLC180117, Exp. June 2021