Enforcement Report - Week of January 22, 2020

Class I Drugs Event

Event ID:
84526

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/10/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Motto International Corp
1908 Royal Ln Ste 700
Dallas TX United States

Distribution Pattern:
TX

Associated Products

Product Description:
Bull Platinum 30000 Capsules, 1000 mg, in orange, white, yellow background with silver text, packaged in 2, 4 and 10 count blister cards, Motto International, Dallas, TX

Product Quantity:
8 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to contain tadalfil

Recall Number:
D-0654-2020

Code Information:
All lots remaining within expiry.

Product Description:
Stallion Platinum 30000 Capsules in blue,orange,white background with red,white text in hologram paper packaging, packaged in 2, 4, 10 count blister cards, Motto International, Dallas, TX

Product Quantity:
7 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to contain tadalfil

Recall Number:
D-0655-2020

Code Information:
All lots remaining within expiry.

Product Description:
Rhino 7 Platinum 30000 Capsules, in blue,orange,black background with red,white,blue,gray text in hologram paper packaging, packaged in 2, 4, and 10 count blister cards, Motto International, Dallas, TX

Product Quantity:
5 boxes

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to contain tadalfil

Recall Number:
D-0656-2020

Code Information:
All lots remaining within expiry.

Product Description:
Panther Platinum 30000 Capsules, in green, black background with white, red text in hologram paper packaging, packaged in 2, 4, and 10 count blister cards, Motto International, Dallas, TX

Product Quantity:
1 box

Reason for Recall:
Marketed without an Approved NDA/ANDA; FDA analysis found product to contain tadalfil

Recall Number:
D-0657-2020

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
84291

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/14/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wisconsin Pharmacal Company, LLC
N168w22223 Main St
Jackson WI United States

Distribution Pattern:
OR

Associated Products

Product Description:
Yeast Arrest, Homeopathic Formula, Vaginal Support suppositories, packaged in a) 14-count carton (NDC 68093-0730-1 and 68093-0730-3), b) 28-count carton (NDC 68093-0730-2 and 68093-0730-4), Manufactured for: Vitanica, 12401 SW Leveton Drive, Tualatin, OR 97062.

Product Quantity:
44,373 cartons

Reason for Recall:
cGMP violations

Recall Number:
D-0781-2020

Code Information:
Lot #: a) 81827, Exp 8/2020; 111872, Exp 11/2020; 41970, Exp 4/2021; 519104, Exp 5/2021; b) 81827, Exp 8/2020; 111872, Exp 11/2020; 41970, Exp 4/2021.

Class II Drugs Event

Event ID:
84546

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Assurance Infusion
2626 S Loop W Ste 555
Houston TX United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Alprostadil 40 mcg/mL (2 mL vial) Inj. Soln. in 2 mL vials Assurance Infusion (713) 533-8800

Product Quantity:
60 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0662-2020

Code Information:
Lots: 09262019@13 Exp. 03/24/2020; 10072019@03/04/2020; 12062019@2 Exp. 06/03/2020; 12172019@12 Exp. 01/31/2020; 08142019@20 Exp. 02/10/2020

Product Description:
Autologous Serum 20% Eye Drops in 3 mL droppers Assurance Infusion (713) 533-8800

Product Quantity:
32 droppers

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0663-2020

Code Information:
Lots: 12092019@33 Exp. 03/08/2020; 11112019@30 Exp. 02/09/2020; 10012019@17 Exp. 12/30/2019; 10162019@18 Exp. 01/14/2020; 10252019@11 Exp. 01/23/2020

Product Description:
BAC 150 mcg/BUP 2 mg/Hydrom 15 mg/Morp 20 mg/SUF 650 mcg/mL Inj. in 20 mL syringe Assurance Infusion (713)533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0664-2020

Code Information:
Lot: 12172019@2 Exp. 12/26/2019

Product Description:
BAC 15MCG/HYDROM 15MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0665-2020

Code Information:
Lot: 12112019@23 Exp. 12/20/2019

Product Description:
BAC 160MCG/HYDROM 16MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0666-2020

Code Information:
Lot: 12112019@20 Exp. 12/20/2019

Product Description:
BAC 200MCG/ CLONI 250MCG/ MORP 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0667-2020

Code Information:
Lot: 12102019@8 Exp. 12/19/2019

Product Description:
BAC 200MCG/BUP22MG/CLON210MCG/HYDROM 15MG/SUF800MCG/ML ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0668-2020

Code Information:
Lot: 12172019@3 Exp. 12/26/2019

Product Description:
BAC 225MCG/ BUP 4.5MG/ CLON 9MCG/ MORP 3MG/ML ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0669-2020

Code Information:
Lot: 12112019@7 Exp. 12/20/2019

Product Description:
BAC 2400MCG/ FENT 2600MCG/ MORP 3600MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0670-2020

Code Information:
Lot: 12102019@2 Exp. 12/19/2019

Product Description:
BAC 250MCG/ /FENT 3500MCG/ /MORP 25MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0671-2020

Code Information:
Lot: 12172019@6 Exp. 12/26/2019

Product Description:
BAC 4000MCG /FENT 600MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0672-2020

Code Information:
Lot: 12162019@16 Exp. 12/25/2019

Product Description:
BAC 400MCG/BUP 20MG/HYDROM 15MG/SUF 1000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0673-2020

Code Information:
Lot: 12202019@2 Exp. 12/20/2019

Product Description:
BAC 50MCG/ HYDROM 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0674-2020

Code Information:
Lot: 12112019@27 Exp. 12/20/2019

Product Description:
BAC 800MCG/BUP 6.7MG/CLON 600 MCG/FENT 850MCG/MORP 20MG INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0675-2020

Code Information:
Lot: 12162019@2 Exp. 12/25/2019

Product Description:
BACLOFEN 2000MCG/ML (40) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0676-2020

Code Information:
Lot: 12112019@18 Exp. 12/20/2019

Product Description:
Bi-Mix 30 mg/1 mg/mL Inj. in 1 mL vials Assurance Infusion (713) 533-8800

Product Quantity:
15 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0677-2020

Code Information:
Lots: 09192019@19 Exp. 03/17/2020; 08162019@5 Exp. 02/12/2020

Product Description:
Bi-Mix Forte 30 mg/2 mg/mL Inj. in 1 mL vials Assurance Infusion (713) 533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0678-2020

Code Information:
Lot: 07302019@15 Exp. 01/29/2020

Product Description:
BPC-157 2000 mcg/mL in 5 mL vials Assurance Infusion (713) 533-8800

Product Quantity:
28 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0679-2020

Code Information:
Lots: 11132019@15 Exp. 02/11/2020; 12112019@25 Exp. 02/13/2020; 11202019@9 Exp. 02/13/2020

Product Description:
BUP 10MG/ FENT 1000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0680-2020

Code Information:
Lot: 12162019@29 Exp. 12/25/2019

Product Description:
BUP 10MG/HYDROM 10MG/MORP 2MG/SUF 250MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0681-2020

Code Information:
Lot: 12112019@8 Exp. 12/20/2019

Product Description:
BUP 10MG/HYDROM 15MG/SUF 200MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0682-2020

Code Information:
Lot: 12162019@4 Exp. 12/25/2019

Product Description:
BUP 15MG/CLON 300MCG/ FENT 1500MCG/ML(40) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0683-2020

Code Information:
Lot: 12122019@6 Exp. 12/21/2019

Product Description:
BUP 15MG/CLON 400MCG/ FENT 6000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0684-2020

Code Information:
Lot: 12132019@5 Exp. 12/22/2019

Product Description:
BUP 15MG/CLON 600MCG/MORP 30MG/ML (40) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0685-2020

Code Information:
Lot: 12182019@2 Exp. 12/27/2019

Product Description:
BUP 15MG/HYDROM 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0686-2020

Code Information:
Lot: 12122019@20 Exp. 12/21/2019

Product Description:
BUP 17MG/MORP 22MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0687-2020

Code Information:
Lot: 12122019@25 Exp. 12/21/2019

Product Description:
BUP 1MG//ML/HYDROM 7MG INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0688-2020

Code Information:
Lot: 12112019@10 Exp. 12/20/2019

Product Description:
BUP 2.5MG/ CLONI 5MCG/ FENT 200MCG/ SUF 50MCG/ML (40) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0689-2020

Code Information:
Lot: 12122019@4 Exp. 12/21/2019

Product Description:
BUP 2.5MG/FENT 25MCG/HYDRO 2MG/MORP 40MG/ML in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0690-2020

Code Information:
Lot: 12102019@3 Exp. 12/19/2019

Product Description:
BUP 20MG/CLON 250MCG/FENT 7200MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0691-2020

Code Information:
Lot: 12172019@5 Exp. 12/26/2019

Product Description:
BUP 20MG/CLON 300MCG/FENT 2000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0692-2020

Code Information:
Lot: 12122019@28 Exp. 12/21/2019

Product Description:
BUP 20MG/SUF 1000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0693-2020

Code Information:
Lot: 12172019@10 Exp. 12/26/2019

Product Description:
BUP 20MG/SUF 105MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0694-2020

Code Information:
Lot: 12122019@8 Exp. 12/21/2019

Product Description:
BUP 21MG/CLON 252MCG/MORP 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0695-2020

Code Information:
Lot: 12182019@1 Exp. 12/27/2019

Product Description:
BUP 23MG/HYDROM 25MG/SUF 100MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0696-2020

Code Information:
Lot: 12162019@15 Exp. 12/25/2019

Product Description:
BUP 2MG/ HYDROM 2MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0697-2020

Code Information:
Lot: 12162019@10 Exp. 12/25/2019

Product Description:
BUP 3.5MG/ HYDROM 4MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0698-2020

Code Information:
Lot: 12122019@27 Exp. 12/21/2019

Product Description:
BUP 30MG/ FENT 400MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0699-2020

Code Information:
Lot: 12132019@3 Exp. 12/22/2019

Product Description:
BUP 30MG/ HYDROM 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0700-2020

Code Information:
Lot: 12122019@23 Exp. 12/21/2019

Product Description:
BUP 30MG/ MORP 8MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0701-2020

Code Information:
Lot: 12122019@11 Exp. 12/21/2019

Product Description:
BUP 30MG/FENT 750MCG/HYDROM 15MG/ML (40) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0702-2020

Code Information:
Lot: 12202019@1 Exp. 12/20/2019

Product Description:
BUP 35MG/FENT 1.5MG/ML in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0703-2020

Code Information:
Lot: 12112019@17 Exp. 12/20/2019

Product Description:
BUP 35MG/MORP 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0704-2020

Code Information:
Lot: 12162019@18 Exp. 12/25/2019

Product Description:
BUP 3MG/HYDROM 15MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0705-2020

Code Information:
Lot: 12162019@1 Exp. 12/25/2019

Product Description:
BUP 3 mg/MORP 15 mg/mL Inj. in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0706-2020

Code Information:
Lots: 12162019@28 Exp. 12/25/2019; 12102019@1 Exp. 12/19/2019

Product Description:
BUP 40MG/FENT 1200MCG/SUF 400MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0707-2020

Code Information:
Lots: 12102019@4 Exp. 12/19/2019

Product Description:
BUP 40MG/FENT 3000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0708-2020

Code Information:
Lots: 12102019@5 Exp. 12/19/2019

Product Description:
BUP 40MG/MORP 4MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0709-2020

Code Information:
Lots: 12172019@4 Exp. 12/26/2019

Product Description:
BUP 4MG/FENT 3000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0710-2020

Code Information:
Lots: 12182019@7 Exp. 12/27/2019

Product Description:
BUP 5.3MG/ FENT 1050 MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0711-2020

Code Information:
Lots: 12112019@5 Exp. 12/20/2019

Product Description:
BUP 5MG/ HYDROM 15MG/ SUF 600MCG/ML (40ML) INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0712-2020

Code Information:
Lots: 12102019@6 Exp. 12/19/2019

Product Description:
BUP 5MG/HYDROM 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0713-2020

Code Information:
Lots: 12122019@26 Exp. 12/21/2019

Product Description:
BUP 5MG/MORP 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0714-2020

Code Information:
Lots: 12122019@21 Exp. 12/21/2019

Product Description:
BUP 5MG/MORP 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0715-2020

Code Information:
Lots: 12162019@6 Exp. 12/25/2019

Product Description:
BUP 675MCG/MORP 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0716-2020

Code Information:
Lots: 12122019@12 Exp. 12/21/2019

Product Description:
BUP 7MG/HYDROM 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0717-2020

Code Information:
Lots: 12182019@4 Exp. 12/27/2019

Product Description:
BUP 8MG/CLON 100MCG/HYDROM 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0718-2020

Code Information:
Lots: 12122019@5 Exp. 12/21/2019

Product Description:
BUP 9MG/ HYDROM 25MG/ SUF 110MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0719-2020

Code Information:
Lots: 12172019@13 Exp. 12/26/2019

Product Description:
CJC-1295 2000 mcg/Ipamorelin 2000 mcg/mL Inj. in 2 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
19 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0720-2020

Code Information:
Lots: 08212019@29 Exp. 02/17/2020; 07152019@12 Exp. 01/11/2020; 07082019@26 Exp. 01/04/2020;

Product Description:
CLON 100MCG/MORP 12MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0721-2020

Code Information:
Lot: 12122019@24 Exp. 12/21/2019

Product Description:
CLON 300MCG/MORP 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0722-2020

Code Information:
Lot: 12132019@8 Exp. 12/22/2019

Product Description:
CLON 500MCG/HYDROM 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0723-2020

Code Information:
Lot: 12162019@22 Exp. 12/25/2019

Product Description:
CLON 750MCG/MORP 30MG/SUF 37.5MCG/ML in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0724-2020

Code Information:
Lot: 12162019@21 Exp. 12/25/2019

Product Description:
CLON 800MCG/FENT 2000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0725-2020

Code Information:
Lot: 12122019@15 Exp. 12/21/2019

Product Description:
FENT 600MCG/ SUF 800MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0726-2020

Code Information:
Lot: 12162019@8 Exp. 12/25/2019

Product Description:
FENT 900MCG/SUF 210MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0727-2020

Code Information:
Lot: 12122019@3 Exp. 12/21/2019

Product Description:
FENTANYL 3000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0728-2020

Code Information:
Lots: 12122019@18 Exp. 12/21/2019; 12162019@24 Exp. 12/25/2019

Product Description:
FENTANYL 1000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0729-2020

Code Information:
Lot: 12182019@3 Exp. 12/27/2019

Product Description:
FENTANYL 100MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0730-2020

Code Information:
Lot: 12162019@11 Exp. 12/25/2019

Product Description:
FENTANYL 2000MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0731-2020

Code Information:
Lot: 12122019@30 Exp. 12/21/2019

Product Description:
FENTANYL 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0732-2020

Code Information:
Lot: 12122019@14 Exp. 12/21/2019

Product Description:
FENTANYL 800MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0733-2020

Code Information:
Lot: 12132019@1 Exp. 12/22/2019

Product Description:
HCG 1,000U/1ML INJ in 4 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0734-2020

Code Information:
Lots: 11252019@27 Exp. 12/29/2019; 11272019@30 Exp. 12/31/2019; 12112019@16 Exp. 01/14/2020; 12062019@7 Exp. 01/09/2020

Product Description:
HCG 10,000U/1ML INJ in 4 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
2 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0735-2020

Code Information:
Lots: 12162019@38 Exp. 01/16/2020; 11272019@32 Exp. 12/31/2019

Product Description:
HCG 3000U/1ML INJ in 4 mL vial Assurance Infusion (713)533-8800

Product Quantity:
2 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0736-2020

Code Information:
Lots: 11272019@31 Exp. 12/31/2019; 12022019@19 Exp. 01/05/2020

Product Description:
HYDROM 10MG/SUF 200MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0737-2020

Code Information:
Lot: 12112019@4 Exp. 12/20/2019

Product Description:
HYDROM 17MG/PRIALT 5MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0738-2020

Code Information:
Lot: 12112019@12 Exp. 12/20/2019

Product Description:
HYDROM 1MG/MORP 20MG/SUF 100MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0739-2020

Code Information:
Lot: 12162019@3 Exp. 12/25/2019

Product Description:
HYDROMORPHONE 15MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0740-2020

Code Information:
Lot: 12162019@7 Exp. 12/25/2019

Product Description:
HYDROMORPHONE 1MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0741-2020

Code Information:
Lot: 12122019@9 Exp. 12/21/2019

Product Description:
HYDROMORPHONE 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0742-2020

Code Information:
Lot: 12122019@17 Exp. 12/21/2019

Product Description:
HYDROMORPHONE 2MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
4 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0743-2020

Code Information:
Lots: 12112019@1 Exp. 12/20/2019; 12112019@6 Exp. 12/20/2019; 12162019@23 Exp. 12/25/2019; 12172019@7 Exp. 12/26/2019

Product Description:
HYDROMORPHONE 3MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0744-2020

Code Information:
Lots: 12162019@14 Exp. 12/25/2019; 12102019@19 Exp. 12/19/2019

Product Description:
HYDROMORPHONE 4MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0745-2020

Code Information:
Lot: 12182019@6 Exp. 12/27/2019

Product Description:
HYDROMORPHONE 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0746-2020

Code Information:
Lot: 12132019@4 Exp. 12/22/2019

Product Description:
HYDROMORPHONE 6MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0747-2020

Code Information:
Lot: 12132019@9 Exp. 12/22/2019

Product Description:
IPAMORELIN 2000MCG/ML INJ in 2 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0748-2020

Code Information:
Lots: 07162019@20 Exp. 01/12/2020; 12102019@17 Exp. 06/07/2020; 07162019@20 Exp. 01/12/2020

Product Description:
LIPO B 25MG/50MG/50MG/1000MCG/ML (10ML VIAL) in 20 mL syringe and 10 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes/1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0749-2020

Code Information:
Lot: 09172019@18 Exp. 03/15/2020

Product Description:
MORP 20MG/SUF 70MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0750-2020

Code Information:
Lot: 12112019@9 Exp. 12/20/2019

Product Description:
MORPHINE 10MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
4 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0751-2020

Code Information:
Lot: 12122019@13 Exp. 12/21/2019; 12172019@9 Exp. 12/26/2019; 12122019@10 Exp. 12/21/2019; 12162019@13 Exp. 12/25/2019

Product Description:
MORPHINE 15MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0752-2020

Code Information:
Lot: 12112019@19 Exp. 12/20/2019

Product Description:
MORPHINE 18MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0753-2020

Code Information:
Lot: 12162019@30 Exp. 12/25/2019

Product Description:
MORPHINE 1MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0754-2020

Code Information:
Lot: 12122019@31 Exp. 12/21/2019; 12172019@8 Exp. 12/26/2019

Product Description:
MORPHINE 20MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
3 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0755-2020

Code Information:
Lot: 12102019@7 Exp. 12/19/2019; 12112019@11 Exp. 12/20/2019; 12162019@5 Exp. 12/25/2019

Product Description:
MORPHINE 2MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0756-2020

Code Information:
Lot: 12162019@20 Exp. 12/25/2019

Product Description:
MORPHINE 30MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0757-2020

Code Information:
Lots: 12132019@6 Exp. 12/22/2019; 12182019@5 Exp. 12/27/2019

Product Description:
MORPHINE 4MG/ML INJ in 20mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
3 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0758-2020

Code Information:
Lots: 12112019@24 Exp. 12/20/2019; 12122019@1 Exp. 12/21/2019; 12122019@2 Exp. 12/21/2019

Product Description:
MORPHINE 5MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0759-2020

Code Information:
Lots: 12122019@7 Exp. 12/21/2019; 12162019@27 Exp. 12/25/2019

Product Description:
MORPHINE 6MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0760-2020

Code Information:
Lot: 12162019@19 Exp. 12/25/2019

Product Description:
MORPHINE 7MG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0761-2020

Code Information:
Lot: 12112019@21 Exp. 12/20/2019

Product Description:
PHENOL 2.5% STERILE SOLUTION in 50 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
2 syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0762-2020

Code Information:
Lot: 10142019@14 Exp. 01/12/2020; 11042019@8 Exp. 02/02/2020

Product Description:
QUADMIX in 1 mL vial Assurance Infusion (713)-533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0763-2020

Code Information:
Lot: 07012019@30 Exp. 12/28/2019

Product Description:
QUADMIX 30MG/2MG/20MCG/100MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
190 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0764-2020

Code Information:
Lots: 07012019@30 Exp. 12/28/2019; 08052019@13 Exp. 02/01/2020; 09252019@15 Exp. 03/23/2020; 10292019@12 Exp. 04/26/2020; 10092019@6 Exp. 03/04/2020; 10162019@12 Exp. 04/13/2020; 12042019@31 Exp. 01/18/2020; 12162019@35 Exp. 01/30/2020; 11262019@37 Exp. 05/24/2020

Product Description:
QUADMIX FORTE in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0765-2020

Code Information:
Lot: 08132019@15 Exp. 02/09/2020

Product Description:
QUADMIX FORTE 30MG/4MG/40MCG/400MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
134 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0766-2020

Code Information:
Lots: 07222019@10 Exp. 01/18/2020; 06242019@19 Exp. 12/21/2019; 08132019@15 Exp. 02/09/2020; 10292019@22 Exp. 04/26/2020; 11272019@24 Exp. 01/22/2020; 09182019@18 Exp. 03/16/2020

Product Description:
SUFENTANIL 150MCG/ML INJ in 20 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0767-2020

Code Information:
Lot: 12162019@26 Exp. 12/25/2019

Product Description:
SUFENTANIL 300MCG/ML INJ in 20 mL syringe Assurance Infusion (713)-533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0768-2020

Code Information:
Lot: 12162019@9 Exp. 12/25/2019

Product Description:
SUFENTANIL 55.5 MCG/ML IN 18ML INJ in 18 mL syringe Assurance Infusion (713) 533-8800

Product Quantity:
1 syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0769-2020

Code Information:
Lot: 12122019@19 Exp. 12/21/2019

Product Description:
TESTOSTERONE CYP 200MG/ML OIL in 10 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0770-2020

Code Information:
Lot: 10242019@7 Exp. 04/21/2020; 10032019@11 Exp. 03/31/2020; 11042019@12 Exp. 05/02/2020; 09242019@9 Exp. 03/22/2020

Product Description:
TESTOSTERONE CYP 200MG/ML OIL (SESAME) INJ in 10 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
7 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0771-2020

Code Information:
Lots: 08212019@17 Exp. 02/17/2020; 10232019@23 Exp. 04/20/2020

Product Description:
TESTOSTERONE CYP 200MG/ML OIL INJ in 10 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
166 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0772-2020

Code Information:
Lots: 09122019@9 Exp. 03/10/2020; 09242019@9 Exp. 03/22/2020; 09192019@20 Exp. 03/17/2020; 10032019@8 Exp. 03/31/2020; 10032019@11 Exp. 03/31/2020; 10182019@5 Exp. 04/15/2020; 10242019@7 Exp. 04/21/2020; 10232019@24 Exp. 04/20/2020; 11042019@12 Exp. 05/02/2020; 11212019@3 Exp. 05/19/2020; 11212019@2 Exp. 05/19/2020; 11042019@15 Exp. 05/02/2020

Product Description:
TRIMIX 30MG/1MG/10MCG/ML INJ in 5 mL/10 mL vials Assurance Infusion (713) 533-8800

Product Quantity:
1290 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0773-2020

Code Information:
Lots: 07082019@29 Exp. 01/04/2020; 06252019@11 Exp. 12/22/2019; 07082019@29 Exp. 01/04/2020; 06252019@6 Exp. 12/22/2019; 07082019@28 Exp. 01/04/2020; 07262019@3 Exp. 01/22/2020; 07102019@13 Exp. 01/06/2020; 07162019@13 Exp. 01/12/2020; 07242019@15 Exp. 01/20/2020; 07162019@12 Exp. 01/12/2020; 08272019@11 Exp. 02/23/2020; 08162019@6 Exp. 02/12/2020; 07312019@14 Exp. 01/27/2020; 07262019@4 Exp. 01/22/2020; 08152019@9 Exp. 02/11/2020; 08162019@6 Exp. 02/12/2020; 08092019@6 Exp. 02/05/2020; 07312019@15 Exp. 01/27/2020; 08092019@5 Exp. 02/05/2020; 08272019@12 Exp. 02/23/2020; 09032019@36 Exp. 03/01/2020; 10012019@19 Exp. 03/30/2020; 09162019@15 Exp. 03/14/2020; 09162019@14 Exp. 03/14/2020; 09032019@35 Exp. 03/01/2020; 09032019@35 Exp. 03/01/2020; 09242019@15 Exp. 03/22/2020; 09112019@5 Exp. 03/09/2020; 10022019@15 Exp. 03/30/2020; 09112019@4 Exp. 03/09/2020; 10162019@16 Exp. 04/13/2020; 10282019@21 Exp. 04/25/2020; 10212019@20 Exp. 03/04/2020; 10162019@15 Exp. 04/13/2020; 10282019@22 Exp. 04/25/2020; 10242019@6 Exp. 03/04/2020; 10232019@25 Exp. 03/04/2020 Exp. 10082019@4 Exp. 04/05/2020; 10082019@5 Exp. 04/05/2020; 11262019@26 Exp. 01/10/2020; 12032019@12 Exp. 01/17/2020; 11262019@25 Exp. 01/10/2020; 10302019@24 Exp. 04/27/2020; 11262019@27 Exp. 01/10/2020; 10302019@23 Exp. 04/27/2020; 12032019@11 Exp. 01/17/2020; 11042019@10 Exp. 03/04/2020; 11042019@10 Exp. 03/04/2020; 11262019@24 Exp. 01/10/2020; 12042019@14 Exp. 01/18/2020; 12042019@15 Exp. 01/18/2020; 12102019@14 Exp. 01/24/2020; 12102019@13 Exp. 01/24/2020

Product Description:
TRIMIX (UA) 30MG/1MG/20MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0774-2020

Code Information:
Lot: 11042019@28 Exp. 05/02/2020

Product Description:
TRIMIX -A (UA) 30MG/1MG/5 MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
10 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0775-2020

Code Information:
Lot: 07082019@31 Exp. 01/04/2020

Product Description:
TRIMIX FORTE 30MG/2MG/20MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
358 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0776-2020

Code Information:
Lots: 08082019@7 Exp. 02/04/2020; 08232019@1 Exp. 02/19/2020; 07262019@12 Exp. 01/22/2020; 07012019@25 Exp. 12/28/2019; 07102019@14 Exp. 01/06/2020; 09202019@4 Exp. 03/18/2020; 10282019@23 Exp. 04/25/2020; 10092019@7 Exp. 03/04/2020; 08292019@11 Exp. 02/25/2020; 10042019@6 Exp. 04/01/2020; 10162019@20 Exp. 04/13/2020; 11062019@24 Exp. 03/04/2020; 12042019@20 Exp. 01/18/2020; 12102019@11 Exp. 01/24/2020; 12162019@36 Exp. 01/30/2020; 11262019@29 Exp. 01/10/2020

Product Description:
TRIMIX FORTE 4 (UA) 30MG/3MG/30MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
10 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0777-2020

Code Information:
Lot: 08302019@4 Exp. 02/26/2020

Product Description:
TRIMIX FORTE PLUS 30MG/4MG/40MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
20 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0778-2020

Code Information:
Lots: 07032019@12 Exp. 12/30/2019; 08212019@32 Exp. 02/17/2020; 10032019@12 Exp. 03/31/2020

Product Description:
TRIMIX SUPER (A) 30MG/2MG/30MCG/ML INJ in 1 mL vial Assurance Infusion (713) 533-8800

Product Quantity:
45 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0779-2020

Code Information:
Lots: 10152019@23 Exp. 03/04/2020; 10302019@27 Exp. 04/27/2020; 08052019@19 Exp. 02/01/2020; 10032019@14 Exp. 03/31/2020

Class II Drugs Event

Event ID:
84570

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Product was distributed throughout the United States to 96 distributors and 1 repacker/relabeler.

Associated Products

Product Description:
Sumatriptan Succinate Tablets, 50 mg, packaged in a) 9 (1x9) Unit-of use blister card (NDC 62756-521-69) and b) 100 count bottles, (NDC 62756-521-88), Rx only, Sun Pharma, Cranbury, NJ

Product Quantity:
384/100 count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications; out-of-specification results obtained for related substance.

Recall Number:
D-0659-2020

Code Information:
a) JKU1939A, JKU1940A, JKU1940B, exp. date 04/2022 and b) JKT4175A, exp. date 11/2020

Product Description:
Sumatriptan Succinate Tablets, 100 mg packaged in 9 (1X9) Unit-of-use blister card, Rx only, Sun Pharma, Cranbury, NJ

Product Quantity:
207,585 blisters

Reason for Recall:
Failed Impurities/Degradation Specifications; out-of-specification results obtained for related substance.

Recall Number:
D-0660-2020

Code Information:
JKT4174A, exp. date 11/2021 JKU0622A, exp. date 01/2022 JKU1308A, exp. date 02/2022

Class II Drugs Event

Event ID:
84672

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Testosterone Cypionate for Injection, USP, 1,000 mg/10 mL (100 mg/mL), 10 mL Multiple Dose Vial (NDC 62756-017-40), Rx only, Distributed by: Sun Pharmaceuticals, Inc., Cranbury, NJ, Manufactured by: Sun Pharmaceuticals, Industries, Ltd., Gujarat, India

Product Quantity:

Reason for Recall:
cGMP Deviations; released lots were manufactured under similar manufacturing conditions to a previously rejected OOS Lot.

Recall Number:
D-0787-2020

Code Information:
JKT0933A, JKT0935A, JKT1062A exp Mar-20; JKT1425A, JKT1483A exp Apr-20; JKT1575A, JKT1729A, JKT1730A, JKT1728A exp May-20 JKT2002A exp Jun-20; JKT3216A, JKT3217A exp Sep-20; JKT3589A, JKT3590A, JKT3626A exp Oct-20; JKT3864A, JKT3935A exp Dec-20

Product Description:
Testosterone Cypionate for Injection, 2,000 mg/10 mL (200 mg/mL), a) 1 mL Single Use vial (NDC 62756-015-40) and b) 10 mL Multiple Dose Vial

(NDC 62756-016-40), Rx only, Distributed by: Sun Pharmaceuticals, Inc., Cranbury, NJ, Manufactured by: Sun Pharmaceuticals, Industries, Ltd., Gujarat, India

Product Quantity:

Reason for Recall:
cGMP Deviations; released lots were manufactured under similar manufacturing conditions to a previously rejected OOS Lot.

Recall Number:
D-0788-2020

Code Information:
a) JKT0075A, JKT0076A, JKT0213A, JKT0215A, JKT0369A, JKT0214A, JKT0368A, JKT0370A exp Jan-20; JKT0371A, JKT0515A, JKT0514A, JKT0516A, JKT0518A, JKT0517A, JKT0694A, JKT0695A, JKT0696A, exp Feb-20; JKT0697A, JKT0698A, JKT1063A, JKT1064A, JKT1065A, JKT1148A, JKT1068A, JKT1146A, JKT1066A exp Mar-20; JKT1149A, JKT1147A, JKT1150A, JKT1427A, JKT1428A, JKT1426A, JKT1429A, JKT1540A, JKT1539A, JKT1541A, JKT1543A, JKT1542A exp Apr-20; JKT1725A, JKT1574A, JKT1727A, JKT1863A, JKT1864A, JKT1865A, JKT1726A exp May-20; JKT2191A exp Jun-20; JKT1866A, JKT2192A, JKT2193A, JKT2194A, JKT2575A, JKT2195A, JKT2576A exp Jul-20; JKT2578A, JKT2579A, JKT2911A, JKT2907A, JKT2908A, JKT2909A, JKT2910A, JKT2577A exp Aug-20; JKT3104A, JKT3105A, JKT3106A, JKT3260A, JKT3261A, JKT3263A, JKT3107A, JKT3467A, JKT3262A, JKT3264A exp Sep-20; JKT3788A, JKT3468A, JKT3749A, JKT3469A, JKT3787A exp Oct-20; JKT3790A, JKT4019A, JKT3789A, JKT4016A, JKT4014A, JKT4017A, Nov-20; JKU0040A exp Dec-20; JKU0041A, JKU0042A, JKU1043A, JKU1044A exp Feb-21; b) JKT1862A, JKT1578A exp May-20; JKT2000A, JKT1999A, JKT2001A exp Jun-20; JKT2593A, JKT2594A exp Jul-20; JKT3863A, JKT4013A exp Nov-20; JKU0037A, JKU0038A, JKU0358A exp Dec-20

Class II Drugs Event

Event ID:
84677

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Dutasteride Capsules, 0.5 mg, 30 Capsules (6 X 5) Unit Dose per carton, Rx Only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478, NDC 50268-282-13.

Product Quantity:
3,989 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: High out of specification results for related compounds.

Recall Number:
D-0661-2020

Code Information:
Lots: 25246, Exp. 02/2021; 24532, Exp. 10/2020; 23647, Exp. 06/2020

Class II Drugs Event

Event ID:
84686

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/15/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Letco Medical LLC
1316 Commerce Dr
Decatur AL United States

Distribution Pattern:
United States, Australia, Canada, Israel, Philippines, Taiwan.

Associated Products

Product Description:
Estriol USP Micronized a) 100 gm NDC 62991-2159-04; b) 1 gm NDC 62991-2159-01; c) 1 kg NDC 62991-2159-06; d) 25 gm NDC 62991-2159-03; e) 500 gm NDC 62991-2159-05; f) 5 gm NDC 62991-2159-02, Rx Only Repackaged by: Letco Medical, LLC. Decatur, AL 35601

Product Quantity:
a) 597 jars; b) 411 jars; c) 5 jars; d) 1004 jars: e) 76 jars; f) 1592 jars

Reason for Recall:
Subpotent

Recall Number:
D-0780-2020

Code Information:
Lots: a) 1804030048 Exp. 06/06/2020; 1712270019, 1802160017 Exp. 08/06/2020; 1804300021, 1806270007, 1808090056, 1904290047 Exp. 04/16/2021; 1810190004, 1812200072, 1901250024 Exp. 08/13/2021; 1902190028, 1907260018 Exp 09/14/2021; b) 1804030049 Exp. 06/06/2020; 1712270020, 1802160018 Exp. 08/06/2020; 1804300022, 1806270008, 1808090057, 1904290048 Exp. 04/16/2021; 1810190005, 1812200073, 1901250025 Exp. 08/13/2021; 1902190029, 1907260019 Exp. 09/14/2021; c) 1802160022 Exp. 08/06/2020; 1810190009, 1812200077 Exp. 08/13/2021; 1907260023 Exp. 09/14/2021; d) 1804030050 Exp 06/06/2020; 1712270021, 1802160019 Exp. 08/06/2020; 1804300023, 1806270009, 1808090058, 1904290049 Exp 04/16/2021; 1810190006, 1812200074, 1901250026 Exp. 08/13/2021; 1902190030, 1907260020 Exp. 09/14/2021; e) 1802160021 Exp. 08/06/2020; 1804300025, 1806270011, 1808090060 Exp. 04/16/2021; 1810190008 Exp. 08/13/2021; 1812200076 Exp. 08/13/2021; 1901250028 Exp. 08/13/2021; 1902190031 Exp. 09/14/2021; 1907260022 Exp. 09/14/2021; f) 1712270022 Exp. 08/06/2020; 1802160020 Exp. 08/06/2020; 1804030051 Exp. 06/06/2020; 1804300024 Exp. 04/16/2021; 1806270010 Exp. 04/16/2021; 1808090059 Exp. 04/16/2021; 1810190007 Exp. 08/13/2021; 1812200075 Exp. 08/13/2021; 1901250027 Exp. 08/13/2021; 1904290050 Exp. 04/16/2021; 1907260021 Exp. 09/14/2021

Class III Drugs Event

Event ID:
84498

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/02/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/17/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Moxifloxacin Ophthalmic Solution USP, 0.5%, Sterile, 3mL Bottle, Rx Only, For Topical Ophthalmic Use Only, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ 08520, Made in India, NDC 65862-840-03.

Product Quantity:
100,080 bottles

Reason for Recall:
Discoloration: Market complaints of discoloration in Moxifloxacin Ophthalmic Solution.

Recall Number:
D-0789-2020

Code Information:
Lot #s: CMF190008; CMF190009, Exp. 04/2021; CMF190025; CMF190026, Exp. 06/2021.

Class III Drugs Event

Event ID:
84674

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/17/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Distributed nationwide in the US

Associated Products

Product Description:
Tri-Lo-Marzia (Norgestimate and Ethinyl Estradiol Tablets, USP), 0.180 mg/0.025 mg; 0.215mg/0.025 mg and 0.250 mg/0.025 mg, Pack size - 3 x 28's wallets/carton, Rx Only, Distributed by Lupin Pharmaceuticals, Inc, Baltimore MD 21202, Manufactured by: Lupin Limited, Pithampur, (M.P.)-454775, India. NDC 68180-837-13 (3x28 carton) NDC 68180-837-11 (28 tablet wallet)

Product Quantity:
34,080 boxes (3 wallets per carton, 80 cartons per box)

Reason for Recall:
CGMP Deviations: Out of specification test result observed during retrospective review of blend uniformity test data.

Recall Number:
D-0790-2020

Code Information:
Lot # L800498, exp. date February 2020

Class III Drugs Event

Event ID:
84678

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sigan Industries Inc.
296 Orenda Rd
Brampton Canada

Distribution Pattern:
IL

Associated Products

Product Description:
Eczema Skin Relief Lotion, 2% Colloidal Oatmeal Skin Protectant Lotion, NET WT 14 OZ (396 g), NDC 65365-266-01, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895.

Product Quantity:
11,004 bottles

Reason for Recall:
Microbial contamination of non-sterile product.

Recall Number:
D-0782-2020

Code Information:
Lot#: 2508-08-337, 2538-08-337, Exp 8/2020

Not Yet Classified Drugs Event

Event ID:
84618

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
01/10/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
McGuff Compounding Pharmacy Services, Inc.
2921 W Macarthur Blvd Ste 142
Santa Ana CA United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Lipoic Acid Injection (aka Alpha Lipoic Acid or Thioctic Acid), 1,200 mg/30 mL (40 mg/mL) Sterile 30 mL Multiple Dose Vial, Rx Only, McGuff Compounding Pharmacy Services, Inc., Santa Ana, CA 92704

Product Quantity:
146 30 ml vials were dispensed

Reason for Recall:
Presence of Particulate Matter: filmy/cloudy particulate observed in vial.

Recall Number:

Code Information:
Lot #: 18M0991, Preparation #: 390-2678, Beyond Usage Date: 06/15/2019