

# Enforcement Report - Week of April 25, 2018

## Class II Drugs Event

**Event ID:**

79580

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

02/21/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/24/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Renaissance Lakewood, LLC

1200 Paco Way

Lakewood NJ United States

**Distribution Pattern:**

Product was distributed throughout the United States.

## Associated Products

**Product Description:**

Fluconazole Injection, USP, Iso-Osmotic Sodium Chloride Diluent, 200 mg in 100 mL (2 mg/mL), package in 100 mL bags, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902, By: Claris Injectables Limited, Sarkhei-Bavla Road, Chacharwadi-Vasna, Ahmedabad, India 382213, NDC 36000-002-10

**Product Quantity:**

1784 bags

**Reason for Recall:**

Labeling: Label mix-up - A complaint was received of one bag of Fluconazole Injection, Iso-Osmotic Sodium Chloride Diluent, USP, 2mg/mL, 50 mL found within the package of 100 mL bags.

**Recall Number:**

D-0696-2018

**Code Information:**

Lot #: A0A0539, Exp. 05/19

## Class II Drugs Event

**Event ID:**

79612

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/27/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/17/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Lupin Pharmaceuticals Inc.

111 S Calvert St Fl 21ST

Baltimore MD United States

**Distribution Pattern:**

Nationwide

## Associated Products

**Product Description:**

Lupin Cefdinir powder for Oral Suspension USP, 250 mg/5 mL in (a) 60 mL packs ( NDC 68180-723-20) and (b) 100 mL packs ( 68180-723-10), Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202

**Product Quantity:**

40,824 bottles

**Reason for Recall:**

Superpotent Drug

**Recall Number:**

D-0684-2018

**Code Information:**

Lot # F602241; Exp. 10/18 Lot # F602577; Exp. 11/18 Lot # F700036; Exp. 12/18

## Class II Drugs Event

**Event ID:**

79619

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/22/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/17/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Partell Specialty Pharmacy  
5835 S Eastern Ave Ste 101  
Las Vegas NV United States

**Distribution Pattern:**

NV only

## Associated Products

**Product Description:**

Ascorbic Acid (Tapioca) 500 mg/mL, 50 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

4 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0634-2018

**Code Information:**

Lot#: 20180201@34, BUD 04/02/2018; 20180202@56, BUD 04/03/2018; 20180129@41, BUD 3/30/2018; 20180207@16, BUD 04/08/2018.

**Product Description:**

B-complex (B1-200mg, B2-4mg, B3-200mg, B5-4mg, B6-4mg) /mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

5 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0635-2018

**Code Information:**

Lot#: 20180205@18, BUD 04/06/2018; 20180126@28, BUD 03/27/2018; 20180126@22, BUD 03/27/2018; 20180205@9, BUD 04/06/2018; 20180214@17, BUD 04/14/2018.

**Product Description:**

Biotin Suspension 10mg/mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

2 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0636-2018

**Code Information:**

Lot #:20180216@10, BUD 5/17/2018; 20180129@25, BUD 04/29/2018.

**Product Description:**

CoEnzymeQ10 25mg/mL, 5mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:**

3 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0637-2018

**Code Information:**

Lot#: 20171227@14, BUD 03/27/2018; 20180205@37, BUD 05/06/2018; 20180214@30, BUD 05/15/2018.

**Product Description:**

Glutathione 200mg/mL, 10mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

four vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0638-2018

**Code Information:**

Lot#: 20180219@58, BUD 05/20/2018; 20180131@15, BUD 05/01/2018; 20180116@9, BUD 04/14/2018; 20180103@5, BUD 04/03/2018.

**Product Description:**

HCG 1000 units/mL, packaged in a) 2 mL and b) 6 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

four vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0639-2018

**Code Information:**

a) Lot#: 20180219@6, BUD 04/05/2018; b) 20180207@14, BUD 03/24/2018; 0180214@22, BUD 03/31/2018; 20180220@7, BUD 04/06/2018.

**Product Description:**

Lipoic Acid 25mg/mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0640-2018

**Code Information:**

Lot#: 20180124@10, BUD 04/05/2018; 20180220@9, BUD 05/21/2018; 20180102@33, BUD 04/02/2018.

**Product Description:**

Methionine 15mg/Inositol 50mg/Choline 100mg, packaged in a) 5mL and b) 50 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

11 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0641-2018

**Code Information:**

a) Lot #: 20180129@18, BUD 4/14/2018 b) Lot #: 20171127@6, 20180207@12, 20180108@16, BUD 04/14/2018.

**Product Description:**

Methionine 25mg/Inositol 50mg/Choline 50mg/ B12 1mg, packaged in a) 5 mL amber vial and b) 50mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0642-2018

**Code Information:**

a) Lot #: 20180123@9, 20171222@11, BUD 4/14/2018, 20180214@7, BUD 08/14/2018. b) Lot #: 20180221@3, BUD 08/21/2018, 20180214@6; BUD 08/14/2018.

**Product Description:**

Nandrolone decanoate 200mg/mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

2 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0643-2018

**Code Information:**

Lot#: 20180221@15, BUD 05/22/2018, 20180123@10, BUD 04/23/2018.

**Product Description:**

Testosterone Cypionate 200mg/mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

7 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0644-2018

**Code Information:**

Lot #: 20180130@2, BUD 7/29/2018; 20180109@1, BUD 07/08/2018; 20180212@51, BUD 08/11/2018; 20171212@4, BUD 06/10/2018; 20180123@6, BUD 07/22/2018; 20171204@4, BUD 06/02/2018; 20171228@15, BUD 03/28/2018.

**Product Description:**

TM #1 (ALP 5.9/PAPAV 17.65/PHEN 0.59) Injectable solution, packaged in 3 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern

Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

15 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0645-2018

**Code Information:**

Lot#: 20180212@22, BUD 03/29/2018; 20180226@64, BUD 04/02/2018.

**Product Description:**

Vitamin D 50,000 unit/ml, 5 mL amber vial, Injectable Liquid, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. # 101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

4 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0646-2018

**Code Information:**

Lot#: 20180220@4, BUD 03/22/2018, 20180221@14, BUD 03/23/2018, 20180228@1, BUD 03/30/2018.

**Product Description:**

Methionine 25mg/Inositol 50mg/Choline 50mg/ B12 1mg, 50 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

1 vial

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0647-2018

**Code Information:**

Lot #: 20180123@4, BUD 4/14/2018.

**Product Description:**

Naltrexone 200 mg pellet, amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0648-2018

**Code Information:**

Lot#: 20180219@90, BUD 08/18/2018

**Product Description:**

Pregnenolone 100 mg (SD) pellet, amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

one vial

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0649-2018

**Code Information:**

Lot#: 20171017@85, BUD: 04/15/2018

**Product Description:**

Progesterone 50 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800 twist top surrounded by a wrapper,

**Product Quantity:**

five vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0650-2018

**Code Information:**

Lot#: 20171220@10, BUD 06/18/201; 20171017@83, BUD 04/15/2018; 20171102@40, BUD 05/01/2018; 20180118@97, BUD 07/17/2018; 00180213@32, BUD 08/12/2018.

**Product Description:**

Testosterone/Anastrozole 120 mg/8 mg pellets packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0651-2018

**Code Information:**

Lot#: 20171220@11, BUD 06/18/2018; 20180201@33, BUD 07/31/2018.

**Product Description:**

Testosterone/Estradiol 60 mg/6 mg pellet Amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800 Testosterone/Finasteride 60 mg/5 mg pellet Amber vial, twist top surrounded by a wrapper Testosterone/Finasteride 80mg/8mg pellet Amber vial, twist top surrounded by a wrapper Testosterone/Finasteride/Anastrozole 120 mg/10 mg/4 mg pellet Amber vial, twist top surrounded by a wrapper

**Product Quantity:**

1 vial

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0652-2018

**Code Information:**

Lot#: 20171010@76, BUD: 04/08/2018.

**Product Description:**

Testosterone/Finasteride 60 mg/5 mg pellet Amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

7 vials

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0653-2018

**Code Information:**

Lot#: 20171012@63, BUD 04/10/2018, 20171127@103, BUD 05/26/2018, 20180115@69, BUD 07/14/2018.

**Product Description:**

Testosterone/Finasteride/Anastrozole 120 mg/10 mg/4 mg pellet Amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**

one vial

**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0654-2018

**Code Information:**

Lot#: 20180111@104, BUD 07/10/2018.

**Product Description:**

Methylcobalamin 12.5 mg/mL, Injectable Liquid, packaged in a) 5 mL amber vial, and b) 50 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0655-2018

**Code Information:**

Lot#: a) 20180119@4, 20171016@10, 20171106@5, 20171214@55, 20180207@5 BUD 04/14/2018; 20180212@15, BUD 03/29/2018; 20180117@26, BUD 07/16/2018. b) 20180219@17, BUD 08/18/2018; 20180205@1, 20180102@39, 20180124@3, BUD 04/14/2018; 20180221@23, BUD 08/20/2018.

**Product Description:**

MVI-7 (B1-100mg/B3-100mg, B5-252 mg, B6-102mg, Vit C-2500 mg, B12-10mg, Mag-1000 mg)/ vial liquid injectable, 50 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0656-2018

**Code Information:**

Lot #: 20180223@1, BUD 04/24/2018; 20180129@5, BUD 03/30/2018; 20180126@4, BUD 03/27/2018; 20180215@22, BUD 04/16/2018; 20180122@10, 20180126@4, BUD 03/23/2018; 20180202@27, BUD 04/03/2018; 20180208@5, 20180201@2, BUD 04/02/2018; # 20180207@2, BUD 04/08/2018, 20180214@11, BUD 04/15/2018; 20180215@22, BUD 04/16/2018.

**Product Description:**

Testosterone Propionate 100mg/mL, 5 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0657-2018

**Code Information:**

Lot #: 20171228@15, BUD 03/28/2018

**Product Description:**

TM #4 (ALP 20/PAPAV/PHENT 2), 3 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0658-2018

**Code Information:**

Lot#: 20180219@27, 20180212@18, BUD 04/02/2018.

**Product Description:**

TM #6 (ALP 25/PAPAV/PHENT1), 3 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0659-2018

**Code Information:**

Lot#: 20180206@7, BUD 03/23/2018, 20180212@41, BUD 03/29/2018, 20180219@40, BUD 04/02/2018.

**Product Description:**

TM (ALP 50/PAPAV 30/PHENT1.5 mg), 3 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0660-2018

**Code Information:**

Lot#: 20180219@31, BUD 04/02/2018; 20180212@42, 20180206@12, BUD 03/29/2018.

**Product Description:**

TM #3 (ALP10/PAPAV12/PHENT1), 3 mL amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0661-2018

**Code Information:**

Lot#: 20180206@3, BUD 03/23/2018; 20180212@15, BUD 03/29/2018, 20180219@16, BUD 04/02/2018.

**Product Description:**

Testosterone 200 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0662-2018

**Code Information:**

Lot#: 20171128@9, BUD 05/27/2018; 20171201@74, BUD 05/30/2018; 20171211@68, BUD 06/09/2018; 20171218@51, BUD 06/16/2018; 20171222@6, BUD 06/20/2018; 20180209@62, BUD 08/08/2018; 20180223@46, BUD 08/22/2018; 20180223@33, BUD 08/22/2018; 20180219@5, BUD 08/18/2018; 20171010@11, BUD 04/08/2018; 20171019@19, BUD 04/17/2018; 20171031@69, BUD 04/29/2018; 20171102@27, BUD 05/01/2018; 20171110@87, BUD 05/09/2018; 20171114@12, BUD 05/13/2018; 20171122@57, BUD 05/21/2018; 20180112@56, BUD 07/11/2018; 20180116@77, BUD 07/15/2018; 20180122@92, BUD 07/21/2018; 20180202@69, BUD 08/01/2018; 20180205@111, BUD 08/04/2018; 20180212@102, BUD 08/11/2018.

**Product Description:**

Testosterone 100 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:**



**Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0663-2018

**Code Information:**

Lot#: 20171212@17, BUD 06/10/2018; 20180205@40, BUD 08/04/2018; 20180208@42, BUD 08/07/2018; 20170929@42, BUD 03/28/2018; 20171013@33, BUD 04/11/2018; 20171020@25, BUD 04/18/2018; 20171025@52, BUD 04/23/2018; 20171101@70, BUD 04/30/2018; 20171106@31, BUD 05/05/2018; 20171116@17, BUD: 05/15/2018, 20171116@42, BUD 05/15/2018; 20180117@87, BUD: 07/16/2018; 20180201@76, BUD 07/31/2018; 20180220@67, BUD 08/19/2018; 20180202@67, BUD 08/01/2018.

**Product Description:**

Testosterone 25 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0664-2018

**Code Information:**

Lot#: 20180130@61, BUD 07/29/2018; 20180208@17, BUD 08/07/2018, 20170928@27, BUD 03/27/2018; 20171025@49, BUD 04/23/2018; 20171109@42, BUD 05/08/2018; 20171117@1, BUD 05/16/2018; 20180130@96, BUD 07/29/2018.

**Product Description:**

Testosterone 37.5 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0665-2018

**Code Information:**

Lot#: 20180220@87, BUD 08/19/2018; 20171113@80, BUD 05/12/2018.

**Product Description:**

Testosterone 40 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0666-2018

**Code Information:**

Lot#: 20171214@90, BUD 06/12/2018; 20171113@81, BUD 05/12/2018; 20180220@58, BUD 08/19/2018.

**Product Description:**

Testosterone 50 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0667-2018

**Code Information:**

Lot#: 0180126@48, BUD 07/25/2018; 20171109@48, BUD 05/08/2018

**Product Description:**

Testosterone 55 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0668-2018

**Code Information:**

Lot#: 20171024@53, BUD 04/22/2018; 20180219@91, BUD 08/18/2018.

**Product Description:**

Testosterone 80 mg pellet packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0669-2018

**Code Information:**

Lot#: 20171213@93, BUD 06/11/2018; 20171220@78, BUD 06/18/2018; 20171017@41, BUD 04/15/2018; 20171117@2, BUD 05/16/2018; 20171213@93, BUD 06/11/2018.

**Product Description:**

Testosterone/Anastrozole 200 mg/20 mg pellets packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0670-2018

**Code Information:**

Lot#: 20171116@3, BUD 05/15/2018; 20180221@72, BUD, 08/20/2018; 20171130@79, BUD 05/29/2018; 20180221@72, BUD 08/20/2018; 20180206@115, BUD 08/05/2018; 20171023@98, BUD 04/21/2018.

**Product Description:**

Testosterone/Anastrozole 60 mg/1 mg pellets packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0671-2018

**Code Information:**

Lot#: 20171130@64, BUD 05/29/2018.

**Product Description:**

Testosterone/Anastrozole 60 mg/4 mg pellets packaged in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0672-2018

**Code Information:**

Lot#: 20171122@65, BUD 05/21/2018; 20171115@56, BUD 05/14/2018; 20171002@77, BUD 03/31/2018; 20171006@63, BUD 04/04/2018; 20171009@55, BUD 04/07/2018; 20171117@72, BUD 05/16/2018.

**Product Description:**

Estradiol 10 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0673-2018

**Code Information:**

Lot#: 20171201@84, BUD: 05/30/2018; 20180125@31, BUD 07/24/2018; 20180209@106, BUD 08/08/2018; 20171011@69, BUD 04/09/2018; 20171019@10, BUD 04/17/2018; 20171106@103, BUD 05/05/2018.

**Product Description:**

Estradiol 12.5 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0674-2018

**Code Information:**

a) Lot#: 20180219@88, 20180208@19, 20180219@45, BUD 08/18/2018.

**Product Description:**

Estradiol 15 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0675-2018

**Code Information:**

Lot#: 20171204@117, BUD 06/02/2018; 20180129@14, BUD 07/28/2018; 20171011@111, BUD 04/09/2018.

**Product Description:**

Estradiol 20 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0676-2018

**Code Information:**

Lot#: 20180129@15, BUD 07/28/2018; 20171207@83, BUD 06/05/2018; 20171016@27, BUD 04/14/2018; 20171204@15, BUD 06/02/2018; 20171006@57, BUD 04/04/2018; 20171018@62, BUD 04/16/2018; 20180116@24, BUD 07/15/2018.

**Product Description:**

Estradiol 25 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0677-2018

**Code Information:**

Lot#: 20171204@15, BUD 06/02/2018; 20171006@57, BUD 04/04/2018; 20171018@62, BUD 04/16/2018; 20180116@24, BUD 07/15/2018.

**Product Description:**

Estradiol 35 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0678-2018

**Code Information:**

Lot: #20171102@42, BUD 05/01/2018.

**Product Description:**

Estradiol 40 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0679-2018

**Code Information:**

Lot#: 20171017@87, BUD 04/15/2018.

**Product Description:**

Estradiol 50 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0680-2018

**Code Information:**

Lot#: 20171009@49, BUD 04/07/2018.

**Product Description:**

Estradiol 55 mg (SD) pellets in amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0681-2018

**Code Information:**

Lot#: 20180104@73, BUD 07/03/2018.

**Product Description:**

Testosterone/Finasteride 80 mg/8 mg pellet, amber vial, Rx only, Partell Specialty Pharmacy, 5835 S. Eastern Ave. #101, Las Vegas, NV 89119 (702) 791-3800.

**Product Quantity:****Reason for Recall:**

Lack of Assurance Sterility: Firm is recalling various drug products due to a non-approved method of sterilization.

**Recall Number:**

D-0682-2018

**Code Information:**

20180110@57, 20180110@23 BUD 07/09/2018, 20171003@91, BUD 04/01/2018, 20171016@24, BUD 04/14/2018.

## Class II Drugs Event

**Event ID:**

79680

**Status:**

Ongoing

**Recall Initiation Date:**

03/30/2018

**Center Classification Date:**

04/17/2018

**Recalling Firm:**

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

**Distribution Pattern:**

Nationwide

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Amantadine HCl Capsules, USP, 100 mg, 50 Capsules (5x10) Unite Dose, Rx Only, Manufactured for: AvKARE Inc. Pulaski, TN 38478 --- NDC 50268-069-15

**Product Quantity:**

2135 cartons

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0633-2018

**Code Information:**

Lot: 16719 Exp. 07/2018

## Class II Drugs Event

**Event ID:**

79689

**Status:**

Ongoing

**Recall Initiation Date:**

03/30/2018

**Center Classification Date:**

04/15/2018

**Recalling Firm:**

Marcas Usa Llc  
222 N Sepulveda Blvd Ste 2000  
El Segundo CA United States

**Distribution Pattern:**

TX

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Press Release

## Associated Products

**Product Description:**

PASTA DE LASSAR ANDROMACO Skin Protection, 25% zinc oxide Topical cream, 60 gram tube, UPC #851357003004, NDC #75940-111-60

**Product Quantity:**

69,238 60 oz. tubes

**Reason for Recall:**

Microbial Contamination of Non-Sterile Products

**Recall Number:**

D-0628-2018

**Code Information:**

Lot Number(s): 15PL041, Exp. 04/18 15PL040, Exp. 04/18 15PL039, Exp. 05/18 17LP117, Exp. 10/20

## Class II Drugs Event

**Event ID:**

79758

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

04/02/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/16/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Diamond Wipes International, Inc.  
4651 Schaefer Ave  
Chino CA United States

**Distribution Pattern:**

Nationwide in the USA.

## Associated Products

**Product Description:**

ACURE, clarifying acne, glycolic + zinc (salicylic acid 0.5%) towelettes, 30-count pouch, Distributed by Better Planet Brands, Fort Lauderdale, FL 33316, UPC 8 54049 00358 0.

**Product Quantity:**

51,840 pouches

**Reason for Recall:**

CGMP Deviations: finished products were manufactured with poor quality water.

**Recall Number:**

D-0629-2018

**Code Information:**

Lot #: A96, A106, B106, EXP 09/18; C27, EXP 01/19

**Product Description:**

WipeEssentials Wet Wipes (benzalkonium chloride 0.13%), 30-count pouches, Dist. by Diamond Wipes Int'l, Inc., Chino, CA 91710, UPC 7 66670 03988 6.

**Product Quantity:**

5,148,792 pouches

**Reason for Recall:**

CGMP Deviations: finished products were manufactured with poor quality water.

**Recall Number:**

D-0630-2018

**Code Information:**

Lot #: 7382A1, 7382B1, 7382A2, 7382B2, 7382A3, 7383A1, 7383B1, 7383A2, 7401A1, 7401B1, 7572A1, 7572B1, 7577B1, 7577A2, 7577B2, EXP 03/18; 7573B1, 7573A2, 7782A1, 7783A1, 7783B1, EXP 04/18; 7984B1, 7984A2, 7984B2, 8043A1, 8043B1, 8403A1, EXP 05/18; 8291A1, 8292B1, 8293A1, 8294B1, EXP 07/18; 8511A1, 8512B1, 8513B1, 8513A2, 8514A1, 8514B1, 8514A2, 8520A1, 8520B1, EXP 08/18; 8818A1, 8821B1, 8821A2, EXP 09/18

## Class II Drugs Event

**Event ID:**

79781

**Status:**

Ongoing

**Recall Initiation Date:**

04/09/2018

**Center Classification Date:**

04/13/2018

**Recalling Firm:**

Noven Pharmaceuticals, Inc.  
11960 SW 144th St  
Miami FL United States

**Distribution Pattern:**

Nationwide.

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Contains: 30 Patches Rx Only NDC 68968-5552-3  
Manufactured for Noven Therapeutics, LLC., Miami, FL 33186 by Noven Pharmaceuticals, Inc. Miami, FL 33186 1-877-567-7857

**Product Quantity:**

9016 boxes of 30 patch each

**Reason for Recall:**

Defective Delivery System: Out of specification for adhesive transfer.

**Recall Number:**

D-0627-2018

**Code Information:**

Lot #: 82237 Exp. May 31, 2018

## Class III Drugs Event

**Event ID:**

79788

**Status:**

Ongoing

**Recall Initiation Date:**

04/06/2018

**Center Classification Date:**

04/16/2018

**Recalling Firm:**

Sandoz Incorporated  
2555 W Midway Blvd  
Broomfield CO United States

**Distribution Pattern:**

Nationwide in the USA and Puerto Rico

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Triamterene and Hydrochlorothiazide Tablets, USP, 75 mg/50 mg, 500-count bottles, Rx only, Manufactured by Sandoz, Inc., Princeton, NJ 08540, NDC 0781-5067-05.

**Product Quantity:**

11,680 bottles

**Reason for Recall:**

Cross Contamination With Other Products: presence of unrelated ingredients (i.e. traces of Lisinopril, Mannitol, Iron, Calcium and Phosphorous).

**Recall Number:**

D-0631-2018

**Code Information:**

Lot #: GW8264, HD3095, Exp 12/18

## Class III Drugs Event

**Event ID:**

79799

**Status:**

Ongoing

**Recall Initiation Date:**

04/10/2018

**Center Classification Date:**

04/17/2018

**Recalling Firm:**Pharmedium Services, LLC  
150 N Field Dr Ste 350  
Lake Forest IL United States**Distribution Pattern:**

MA, WA

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Telephone

## Associated Products

**Product Description:**

Vasopressin 50 Units added to 250 mL 0.9% Sodium Chloride Injection USP (0.2 units per mL), Rx only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478

**Product Quantity:**

72 bags

**Reason for Recall:**

cGMP deviations

**Recall Number:**

D-0632-2018

**Code Information:**

Lot: 180660057S Exp. 6/5/2018

## Class III Drugs Event

**Event ID:**

79849

**Status:**

Ongoing

**Recall Initiation Date:**

04/09/2018

**Center Classification Date:**

04/17/2018

**Recalling Firm:**

LEADIANT BIOSCIENCES, INC

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Letter



9841 Washingtonian Blvd Ste 500  
Gaithersburg MD United States

**Distribution Pattern:**

Walgreens Specialty Pharmacy Pittsburg, PA Italy and Germany

## Associated Products

**Product Description:**

Cystaran (cysteamine ophthalmic solution) 0.44%, 15 mL bottle, Rx only, Manufactured by Hi-Tech Pharmacal Co. Inc. Amityville, NY 11701 for Leadiant Biosciences, Inc. Gaithersburg, MD 20878, NDC 54482-020-01

**Product Quantity:**

3,398 bottles

**Reason for Recall:**

Subpotent drug: Out of specification for an active ingredient cysteamine hydrochloride.

**Recall Number:**

D-0683-2018

**Code Information:**

lot numbers: 35866, Exp 6/18; 358663, Exp 7/18