

# Enforcement Report - Week of November 1, 2017

## Class I Drugs Event

<b>Event ID:</b> 77841	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 06/22/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/24/2017	<b>Initial Firm Notification of Consignee or Public:</b> Press Release
<b>Recalling Firm:</b> Vitality 7283 Florin Mall Dr Apt #3 Sacramento CA United States		<b>Distribution Pattern:</b> Nationwide in the USA	

## Associated Products

<b>Product Description:</b> MAN OF STEEL capsules, 3000mgs/grain, 1-count packets, Packaged for: One Drop Solutions, LLC, POB 231693, Sacramento, California 95823; vitality@yahoo.com; www.manofsteelpills.com; UPC 1 0001001378 7.	<b>Product Quantity:</b> 75 packets
<b>Reason for Recall:</b> Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making this an unapproved drug for which safety and efficacy have not been established and therefore, subject to recall.	<b>Recall Number:</b> D-0032-2018
<b>Code Information:</b> No Lot #: labeled Expires: 10-17-2018	

## Class I Drugs Event

<b>Event ID:</b> 78051	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 08/29/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/24/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Lucky Mart Inc. 2210 N Seaman Ave South El Monte CA United States		<b>Distribution Pattern:</b> Nationwide in the USA	

## Associated Products

<b>Product Description:</b> PIYANPING Anti-Itch (hydrocortisone) Lotion, 1%, Net Wt. 0.67 oz (20g) tube, Manufactured By: Jimin Pharmaceutal Co., LTD., Distributor: Lucky Mart, El Monte, CA 91733, NDC 68085-8012-4.	<b>Product Quantity:</b> 13,800 tubes
<b>Reason for Recall:</b> Incorrect Product Formulation: product contains dexamethasone instead of hydrocortisone.	<b>Recall Number:</b> D-0031-2018
<b>Code Information:</b> Lot #: C16001, C16002, Exp 12/18	

## Class I Drugs Event

<b>Event ID:</b> 78155	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/15/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/24/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield IL United States		<b>Distribution Pattern:</b> Impacted shipment sent to Wholesalers, Medical Facilities and Physicians in CA and NV, but could have been further distributed Nationwide in the USA.	

### Associated Products

<b>Product Description:</b> Intralipid 20%, A 20% I.V. Fat Emulsion, 100 ml bag, Rx only, Manufactured by Fresenius Kabi, Uppsala, Sweden for Baxter Healthcare Corporation, Deerfield, IL 60015 USA, NDC 0338-0519-58	<b>Product Quantity:</b> 910 bags
<b>Reason for Recall:</b> Temperature Abuse: A portion of this product lot was exposed to subfreezing temperatures, which is outside of the acceptable storage range listed on the product labeling, during transit to a distribution facility.	<b>Recall Number:</b> D-0030-2018
<b>Code Information:</b> Lot #: 10LE9597, Exp 04/01/19	

## Class II Drugs Event

<b>Event ID:</b> 78063	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/01/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/25/2017	<b>Initial Firm Notification of Consignee or Public:</b> Press Release
<b>Recalling Firm:</b> Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest IL United States		<b>Distribution Pattern:</b> Nationwide.	

### Associated Products

<b>Product Description:</b> Oxytocin 10 units added to 1000 mL Lactated Ringer's Injection USP in 1000 mL bag, Rx Only , Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130, Sugar Land, TX 77478, NDC# 71019-237-03	<b>Product Quantity:</b> 564 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0035-2018
<b>Code Information:</b> All unexpired lots.	

  

<b>Product Description:</b> Oxytocin 10 units added to 500 mL Lactated Ringer's Injection USP in 500 mL bag ,Rx Only , Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130, Sugar Land, TX 77478, NDC# 71019-237-01	<b>Product Quantity:</b> 1308 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0036-2018

<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 15 units added to 250 mL Lactated Ringer's Injection USP in 250 mL bag, Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130, Sugar Land, TX 77478, NDC# 71019-239-01	<b>Product Quantity:</b> 2232 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0037-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 20 units added to 1000 mL Lactated Ringer's Injection USP in 1000 mL bag, Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-241-06	<b>Product Quantity:</b> Unknown
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0038-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 20 units added to 1000 mL Lactated Ringer's Injection USP in 1000 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-241-04	<b>Product Quantity:</b> 390 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0039-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 20 units added to 1000 mL Lactated Ringer's Injection USP in 1000 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-241-05.	<b>Product Quantity:</b> 978 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0040-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 20 units added to 500 mL Lactated Ringer's Injection USP in 500 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-241-03	<b>Product Quantity:</b> 60 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0041-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 30 units added to 1000 mL 5% Dextrose/Lactated Ringer's USP in 1000 mL bag, Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-242-02	<b>Product Quantity:</b> 534 bags
<b>Reason for Recall:</b> Subpotent Drug	<b>Recall Number:</b> D-0042-2018
<b>Code Information:</b> All unexpired lots.	
<b>Product Description:</b> Oxytocin 30 units added to 500 mL 5% Dextrose/Lactated Ringer's USP in 500 mL bag, Rx Only, Compounded	<b>Product Quantity:</b> 4452 bags

by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-242-01

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0043-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 30 units added to 500 mL Lactated Ringer's USP in 500 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130, Sugar Land, TX 77478, NDC# 71019-243-01

**Product Quantity:**

6108 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0044-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 30 units added to 1000 mL Lactated Ringer's USP in 1000 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-243-04

**Product Quantity:**

763 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0045-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 40 units added to 1000 mL Lactated Ringer's USP in 1000 mL bag Rx Only , Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-245-02

**Product Quantity:**

1152 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0046-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 30 units added to 500 mL Lactated Ringer's USP in 500 mL bag, Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-243-03

**Product Quantity:**

24486 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0047-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 40 units added to 1000 mL Lactated Ringer's USP in 1000 mL bag, Rx Only , Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130, Sugar Land, TX 77478, NDC# 71019-245-03

**Product Quantity:**

90 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0048-2018

**Code Information:**

All unexpired lots.

**Product Description:**

Oxytocin 40 units added to 1000 mL Lactated Ringer's USP in 1000 mL bag Rx Only, Compounded by PharMEDium Services, LLC. 12620 W. Airport Blvd. #130 Sugar Land, TX 77478, NDC# 71019-245-04

**Product Quantity:**

42 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0049-2018

**Code Information:**

All unexpired lots.

**Class II Drugs Event**

<b>Event ID:</b> 78227	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 10/10/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/23/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Banner Pharmacy Services, LLC 7300 W Detroit St Chandler AZ United States		<b>Distribution Pattern:</b> Nationwide within the US	

**Associated Products**

<b>Product Description:</b> Diltiazem HCL 125 mg added to 0.9% Sodium Chloride 100 ml bag, 125 mL bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 85226, NDC 7025018601	<b>Product Quantity:</b> 1359 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0015-2018
<b>Code Information:</b> Lot #: 071817S1, Exp 10/18/2017; 072417S1, Exp 10/24/2017; 072517S1, Exp 10/25/2017; 081117S1, Exp 11/11/2017; 081517S1, Exp 11/15/2017; 082217S1, Exp 11/22/2017	
<b>Product Description:</b> ePHEDrine sulfate 50 mg/10 ml syringes in 0.9% Sodium Chloride, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 85226, NDC 7025024801	<b>Product Quantity:</b> 972 syringes
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0016-2018
<b>Code Information:</b> Lot #: 072717S1, Exp 10/25/2017; 080217S1, 10/31/2017; 081517S2, Exp 11/13/2017; 082917S1, Exp 11/27/2017.	
<b>Product Description:</b> fentaNYL citrate 1000 mcg (10 mcg/mL) 100 mL Cassette in 0.9% Sodium Chloride, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 85226, NDC 7025011001	<b>Product Quantity:</b> 9030 cassetts
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0017-2018
<b>Code Information:</b> Lot #: 041317S1, Exp 10/10/2017; 041817S1, Exp 10/15/2017; 042017S1, 10/17/2017; 042517S1, 10/22/2017; 042717S1, Exp 10/24/2017; 050217S1, Exp 10/29/2017; 050417S2, Exp 10/31/2017; 050917S1, 11/5/2017; 051117S1, 051117S4, 11/7/2017; 051617S1, 11/12/2017; 051817S1, Exp 11/14/2017; 052317S1, Exp 11/19/2017; 053017S1, Exp 11/26/2017; 060617S1, Exp 12/3/2017; 060917S1, Exp 12/6/2017; 061317S1, Exp 12/10/2017; 061517S2, Exp 12/12/2017; 062017S1, Exp 12/17/2017; 062217S1, Exp 12/19/2017; 062717S1, Exp 12/24/2017; 62817S1, Exp 12/25/2017; 070417S1, Exp 12/31/2017; 070517S1, Exp 1/1/2018; 071317S1, Exp 1/7/2018; 071817S2, Exp 1/14/2018; 072017S1, Exp 1/16/2018; 72517S2, Exp 1/21/2018; 080817S1, Exp 2/4/2018; 080917S1, Exp 2/5/2018; 081617S1, Exp 2/12/2018; 081717S1, Exp 2/13/2018.	
<b>Product Description:</b> fentanyl citrate (PF) 1100 mcg (20 mcg/mL) 55 mL syringes in 0.9% Sodium Chloride, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025011001	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0018-2018

<b>Code Information:</b> Lot # :051717S1, Exp 11/13/2017; 052417S1, Exp 11/20/2017; 062117S1, Exp 12/18/2017; 071217S1, Exp. 1/8/2017; 071917S1, Exp 1/15/2018; 072617S1, Exp 1/22/2018; 081017S1, Exp 2/6/2018	
<b>Product Description:</b> Hydromorphone HCl 10 mg (0.2mg/ml) 50 mL syringes in 0.9% Sodium Chloride, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025001001.	<b>Product Quantity:</b> 1658 syringes
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0019-2018
<b>Code Information:</b> Lot #: 041817S5, Exp 10/15/2017; 052417S2, Exp 11/20/2017; 071117S4, Exp 1/7/2018; 0712217S4, Exp 1/8/2018; 080317S6, Exp 1/30/2018; 082217S5, Exp 2/1/2018	
<b>Product Description:</b> Magnesium sulfate 10 Gm added to Lactated Ringer's 250 mL bags, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025003201	<b>Product Quantity:</b> 7578 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0020-2018
<b>Code Information:</b> Lot #: 042017S4, Exp 10/20/2017; 042517S2, 10/25/2017; 042617S3, Exp 10/26/2017; 050317S2, Exp 11/2/2017; 050517S3, Exp 11/4/2017; 051217S2, Exp 11/11/2017; 051917S1, Exp 11/18/2017; 052917S4, Exp 11/28/2017; 061317S5, Exp 12/13/2017; 061617S1, Exp 12/16/2017; 062317S1, Exp 12/23/2017; 062817S2, 12/28/2017; 062917S1, Exp 12/29/2017; 070717S1, Exp 1/6/2018; 071317S4, Exp 1/12/2018; 072017S3, Exp 1/19/2018; 072617S6, Exp 1/25/2018; 072717S3, Exp 1/26/2018; 073117S1, Exp 1/30/2018; 080317S2, Exp 2/2/2018; 080717S1, Exp 2/6/2018; 081017S3, Exp 2/9/2018; 081717S2, Exp 2/16/2018; 082417S2, 082417S5 Exp 2/23/2018;	
<b>Product Description:</b> Midazolam HCL 100 mg (1mg/mL) 100 mL Cassette in 0.9% Sodium Chloride, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025016201	<b>Product Quantity:</b> 966 cassettes
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0021-2018
<b>Code Information:</b> Lot #: 042617S4, Exp 10/23/2017; 060817S1, Exp 12/5/2017; 070517S2, Exp 1/1/2018; 072817S1, Exp 1/24/2018; 080117S2, Exp 1/28/2018; 083017S1, Exp, 2/26/2018	
<b>Product Description:</b> Norepinephrine Bitartrate 8 mg added to 0.9% Sodium Chloride 250 mL in a bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025011501	<b>Product Quantity:</b> 3550 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0022-2018
<b>Code Information:</b> Lot #: 071217S2, Exp 10/11/2017; 071417S1, Exp 10/13/2017; 071917S2, 071917S3, Exp 10/18/2017; 072117S1, Exp 10/20/2017; 072617S2, 072617S3, Exp 10/25/2017; 072817S2, Exp 10/27/2017; 073117S2, 10/30/2017; 080217S2, Exp 11/1/2017; 080717S2, Exp 11/6/2017; 081117S2, Exp 11/10/2017; 081417S2, Exp 11/13/2017; 081617S2, Exp 11/15/2017; 082217S2, Exp 11/21/2017; 082317S2, Exp 11/22/2017 ; 082917S2, Exp 11/28/2019	
<b>Product Description:</b> OXYtocin 30 units added to 0.9% Sodium Chloride 500 mL bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025000101	<b>Product Quantity:</b> 24306 units
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0023-2018
<b>Code Information:</b> Lot#: 072017S4, Exp 11/16/2017; 072117S2, Exp 11/17/2017; 072417S2, Exp 11/20/2017; 072717S5, Exp 11/23/2017; 072817S3, Exp 11/24/2017; 073117S3, Exp 11/27/2017; 080217S3, Exp 11/29/2017; 080317S3, Exp 11/30/2017; 080917S3, Exp 12/6/2017; 081117S4, Exp 12/8/2017; 081717S3, Exp 12/14/2017; 081817S1, Exp 12/15/2017; 082217S3, Exp 12/19/2017; 082317S3, 082317S5, Exp 12/20/2017; 082417S3, Exp 12/21/2017; 082517S2, Exp 12/22/2017.	

<b>Product Description:</b> Ropivacaine HCL (PF) 0.2% (2mg/mL) 100 mL Cassette Rx Only Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226 NDC 7025006301	<b>Product Quantity:</b> 2173 cassettes
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0024-2018
<b>Code Information:</b> Lot #: 041117S2, Exp 10/11/2017; 041817S3, Exp 10/18/2017; 042517S3, 10/25/2017; 050117S2, Exp 10/3102/17; 053017S3, Exp 11/29/2017; 06017S3, Exp 12/11/2017; 060617S3, Exp 12/6/2017; 061217S1, 12/12/2017; 062017S3, Exp 12/20/2017; 062717S2, Exp 12/27/2017; 062817S3, Exp 12/28/2017; 071117S2, Exp 1/10/2018; 071817S3, Exp 1/17/2018; 072117S3, Exp 1/20/2018; 072417S3, Exp 1/23/2018; 072517S3, Exp 1/24/2018; 080217S4, Exp 2/1/2018; 081117S3, Exp 2/10/2018; 081817S2, Exp 2/17/2018; 082317S4, Exp 2/22/2018.	
<b>Product Description:</b> Succinylcholine 200 mg/10 mL Syringe, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025088801	<b>Product Quantity:</b> 2792 syringes
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0025-2018
<b>Code Information:</b> Lot #: 071917S5 Exp 10/17/2017; , 072717S7, Exp 10/25/2017; 080817S3, Exp 11/6/2017; 082317S6, Exp 11/21/2017; 082417S6, Exp 11/22/2017; 082517S3, Exp 11/23/2017.	
<b>Product Description:</b> VANCOmycin 1.5 grams added to 0.9% Sodium Chloride 500 mL bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025002501	<b>Product Quantity:</b> 3136 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0026-2018
<b>Code Information:</b> Lot #: 082817S3, Exp. 10/14/2017	
<b>Product Description:</b> VANCOmycin 1.25 grams added to 0.9% Sodium Chloride 500 mL bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 95226, NDC 7025007001	<b>Product Quantity:</b> 2443 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0027-2018
<b>Code Information:</b> Lot #: 082817S2, Exp 10/14/2017	
<b>Product Description:</b> Norepinephrine Bitartrate 16 mg added to 0.9% Sodium Chloride 250 mL bag, Rx Only, Banner Health Compounding Pharmacy 7300 W Detroit St Chandler, AZ 85226, NDC 7025014801	<b>Product Quantity:</b> 481 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility.	<b>Recall Number:</b> D-0028-2018
<b>Code Information:</b> Lot #: 072717S4, Exp 10/26/2017; 080917S2, Exp 11/8/2017; 082517S1, Exp 11/24/2017	

### Class III Drugs Event

<b>Event ID:</b> 77951	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 08/22/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/26/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter

**Recalling Firm:**  
Wockhardt Usa Inc.  
20 Waterview Blvd Ste 3  
Parsippany NJ United States

**Distribution Pattern:**  
Nationwide in the USA

### Associated Products

<b>Product Description:</b> Enalapril Maleate tablets, USP, 5mg, 1000-count bottles, Rx only, Manufactured by: Wockhardt Limited H-14/2, M.I.D.C. Area, Waluj, Aurangabad, Maharashtra, India, Distributed by: Wockhardt, USA LLC, 20 Waterview Blvd, Parsippany, NJ 07054, USA. NDC: 64679-924-03;	<b>Product Quantity:</b> 5050 bottles
<b>Reason for Recall:</b> Failed Impurities/Degradation Specifications: 5mg strength being recalled for out of specification results for related compound.	<b>Recall Number:</b> D-0051-2018
<b>Code Information:</b> Lot # DR10635, EXP 05/2019; DR10636, EXP 05/2019.	

### Class III Drugs Event

<b>Event ID:</b> 78106	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/05/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/26/2017	<b>Initial Firm Notification of Consignee or Public:</b> E-Mail

**Recalling Firm:**  
Aidarex Pharmaceuticals LLC  
595 N Smith Ave Ste B  
Corona CA United States

**Distribution Pattern:**  
Product was distributed in Florida

### Associated Products

<b>Product Description:</b> ENALAPRIL MALEATE Tablets, USP, 5MG, 90-count bottles, Rx only, MFG: Wockhardt Ltd., India; Packaged By: Aidarex Pharmaceuticals; NDC 33261-0693-90.	<b>Product Quantity:</b> 12 bottles
<b>Reason for Recall:</b> Failed Impurities/Degradation Specifications: manufacturer of product recalled this repackaged lot due to out of specification results for related compound.	<b>Recall Number:</b> D-0053-2018
<b>Code Information:</b> Lot #: 55097-2, 56085-1, Exp 11/30/2018	

### Class III Drugs Event

<b>Event ID:</b> 78308	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 10/17/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/26/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter

**Recalling Firm:**  
Teva Pharmaceuticals USA

**Distribution Pattern:**  
Nationwide in the USA and Puerto Rico



1090 Horsham Rd  
North Wales PA United States

### Associated Products

<b>Product Description:</b> Methylphenidate Hydrochloride Tablets USP, 20 mg, 100-count bottles, Rx only, Manufactured by: Watson Laboratories, Inc., Corona, CA 92880 USA, NDC 0591-5884-01.	<b>Product Quantity:</b> 58,292 bottles
<b>Reason for Recall:</b> Failed Dissolution Specifications: Low out of specification results for dissolution.	<b>Recall Number:</b> D-0052-2018
<b>Code Information:</b> Lot Number # 1156086M, Exp 08/18	

### Not Yet Classified Drugs Event

<b>Event ID:</b> 78101	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/13/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Vi-Jon, Inc. 1 Swan Dr Smyrna TN United States		<b>Distribution Pattern:</b> Nationwide.	

### Associated Products

<b>Product Description:</b> Equate Beauty Clarifying Face Daily Moisturizer 4 fl. oz. (118 mL) NDC# 4903594126 UPC# 681131150774 Distributed by: Wal-Mart Stores, Inc. Bentonville, AR 72716; Studio 35 Beauty Daily Clarifying Face Daily Moisturizer 4 fl. oz. (118 mL) NDC# 0363001726 UPC# 049022889125 Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015	<b>Product Quantity:</b> 67532 bottles
<b>Reason for Recall:</b> Out of specification results for stability shelf life.	<b>Recall Number:</b>
<b>Code Information:</b> Lots: 0307223 Exp. 12/2017; 0345361 Exp. 02/2019; 0342373 Exp. 12/2018; 0342656 Exp. 12/2018	