

## Enforcement Report - Week of March 22, 2017

### Class II Drugs Event

**Event ID:**  
76357

**Status:**  
Ongoing

**Recall Initiation Date:**  
01/19/2017

**Center Classification Date:**  
03/10/2017

**Recalling Firm:**  
Mylan Pharmaceuticals Inc.  
781 Chestnut Ridge Rd  
Morgantown WV United States

**Distribution Pattern:**  
Nationwide

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**  
E-Mail

### Associated Products

**Product Description:**

Mirtazapine Tablets, USP 45 mg, a) 30 count, b) 100 count and c) 500 count bottles, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV

**Product Quantity:**

37,445 bottles

**Reason for Recall:**

Presence of Foreign Tablets/Capsules; possibility of Glipizide 10 mg tablet in bottle

**Recall Number:**

D-0492-2017

**Code Information:**

a) 3078937 and 3078938 (NDC 0378-3545-93), exp August 2019 b) 3078937 (NDC 0378-3545-01), exp August 2019 c) 3078936 (0378-3545-05), exp August 2019

### Class II Drugs Event

**Event ID:**  
76432

**Status:**  
Ongoing

**Recall Initiation Date:**  
02/07/2017

**Center Classification Date:**  
03/10/2017

**Recalling Firm:**  
Teva Pharmaceuticals USA  
1090 Horsham Rd  
North Wales PA 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:**

Buprenorphine and Naloxone Sublingual Tablets 8 mg/2 mg, 30 count HDPE bottles, Rx Only, Distributed by TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC 0093-5721-56

**Product Quantity:**

7,628 HDPE bottles (228,840 tablets)

**Reason for Recall:**

Failed Impurities/Degradation Specifications

**Recall Number:**

D-0517-2017

**Code Information:**

Lot 30227056A; Exp. 03/17

### Class II Drugs Event

**Event ID:**  
76463

**Status:**  
Ongoing

**Recall Initiation Date:**  
01/27/2017

**Center Classification Date:**  
03/10/2017

**Recalling Firm:**  
Mylan Institutional, Inc. (d.b.a. UDL Laboratories)  
1718 Northrock Ct  
Rockford IL 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:**  
Mirtazapine Tablets, USP, 45 mg. Rx only, 100 Tablets (10 X 10). Manufactured by: Mylan Pharmaceuticals Inc, Morgantown, WV

**Product Quantity:**  
58 UD100 Unit Does Blister Cards of 10 (10 cards of 10 tablets each)

**Reason for Recall:**  
Presence of Foreign Tablets/Capsules; possibility of Glipizide 10 mg tablets commingled

**Recall Number:**  
D-0493-2017

**Code Information:**  
Batch #3083289; Exp. Date 12/2018

**Class II Drugs Event**

**Event ID:**  
76472

**Status:**  
Ongoing

**Recall Initiation Date:**  
02/10/2017

**Center Classification Date:**  
03/15/2017

**Recalling Firm:**  
Synergy Rx  
4901 Morena Blvd Ste 504A  
San Diego CA United States

**Distribution Pattern:**  
Nationwide within the United States

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

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

**Associated Products**

**Product Description:**  
Human Chorionic Gonadotropin (HCG) 5,000 units/vial and 11,000 units/vial, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

**Product Quantity:**  
1809 vials

**Reason for Recall:**  
Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**  
D-0522-2017

**Code Information:**  
All Lots

**Product Description:**  
CANTHARADIN 0.7% SOLUTION and CANTHARIDAN / PODOPHYLLUM SOLUTION, CANTHARIDIN/PODOPHYLLUM RESIN MIXTURE, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

**Product Quantity:**

**Reason for Recall:**  
Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**  
D-0523-2017

**Code Information:**  
All Lots

**Product Description:**  
HCG and HCG with resveratrol Human Chorionic Gonadotropin in different strengths: HCG 300 UNITS/RESVERATROL 50MG S.L. Tablet, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

**Product Quantity:**

**Reason for Recall:**  
Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**  
D-0524-2017

**Code Information:**  
All Lots

**Product Description:**  
KETOCONAZOLE 2%/HYDROCORTISONE 1.5% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676.

**Product Quantity:**

**Reason for Recall:**  
Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**  
D-0525-2017

**Code Information:**  
All Lots

**Product Description:**  
TACROLIMUS 0.1% Ointment and TACROLIMUS 0.1%/KETOCONAZOLE 2%, Rx only, Synergy Rx, 4901 Morena Blvd #504-A San Diego, CA 92117 (855) 792-6676

**Product Quantity:**

**Reason for Recall:**  
Lack of Assurance of Sterility: There are also CGMP Deviations.

<b>Recall Number:</b> D-0526-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> 5-FLUOROURACIL IN VANICREAM, FLUOROURACIL in all strengths including 0.05%, 5% CREAM, FLUOROURACIL 4.9% IN CERAVE CREAM, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0527-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> MINOXADIL all strength including 2%, 5% and MINOXIDIL / RETINOIC ACID 5% / 0.025, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0528-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> BICARBONATE 10%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0529-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> ADAPALENE 0.1%, BENZOYL PEROXIDE 2.5% GEL, ADAPELENE 0.3%, BENZOYL PEROXIDE 2.5% GEL, AZELAIC ACID 15% CREAM, AZELAIC ACID 20% IN OI FREE CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0530-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> BENZOYL PEROXIDE 5% CLINDAMYCIN 1.2%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0531-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> BL 20%/4% CREAM, BLT 20%/6%/4% CREAM, BLT 20% 8% 4% CREAM, BLT 20% 8% 4% OINTMENT, BLT 20% 8% 6% CREAM, BLT 20%/ 8% /8% OINTMENT, BLT 20%/ 8% /8% CREAM, BLT 20%/ 7% / 7% CREAM, BLT 20%/ 10%/ 4% CREAM, BLT 20%/ 10%/ 10% CREAM, BLT 20%/ 20%/ 10% OINTMENT, BLT 7%/ 10%/ 7% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0532-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> BLEACHING CREAM 0.1% CREAM, BLEACHING CREAM HQ4%, BLEACHING CREAM-NO HQ, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676  <b>Product Quantity:</b>  <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.  <b>Recall Number:</b> D-0533-2017  <b>Code Information:</b> All Lots
<b>Product Description:</b> CLINDAMYCIN 1%, AZELAIC ACID 10% CREAM, CLINDAMYCIN 1.2%/ TRETINOIN 0.05% GEL, CLINDAMYCIN 1.2%/ TRETINOIN 0.1% GEL CLINDAMYCIN 2.5%, BENZOYL PEROXIDE 5%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0534-2017

**Code Information:**

All Lots

**Product Description:**

CLOBETASOL 0.05% IN OLEA BASE, CLOBETASOL 0.05% IN OROBASE, CLOBETASOL 0.05% OINTMENT, CLOBETASOL 0.05%/ SODIUM, SULFACETAMIDE 10% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0535-2017

**Code Information:**

All Lots

**Product Description:**

ERYTHROMYCIN 2% IN CERAVE CREAM, ERYTHROMYCIN 3% / RETINOIC ACID 0.05%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0536-2017

**Code Information:**

All Lots

**Product Description:**

FLUORORACIL 0.05% CREAM, FLUORORACIL 5% CREAM, FLUOROURACIL 4.9% IN CERAVE CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0537-2017

**Code Information:**

All Lots

**Product Description:**

FLUOCINONIDE 0.05% SOLUTION, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0538-2017

**Code Information:**

All Lots

**Product Description:**

GLYCOLIC ACID 15% LOTION, GLYCOLIC ACID 20% GEL, GLYCOLIC ACID 6% LOTION, GLYCOLIC ACID 5% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0539-2017

**Code Information:**

All Lots

**Product Description:**

GLYCOLIC ACID SOLUTION, all strengths including 10%, 20%, 30%, 50%, and 60%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0540-2017

**Code Information:**

All Lots

**Product Description:**

RETINOIC ACID all strengths including 0.025%, 0.05% and 0.1% CREAM, RETINOIC ACID 0.025%/CLINDAMYCIN 1.2% GEL, RETINOIC ACID 0.025%/ HYALURONIC ACID CREAM, RETINOIC ACID 0.05%/HYALURONIC ACID CREAM, RETINOIC ACID 0.1% IN CERAVE CREAM, RETINOIC ACID POWDER 1 GRAM, RETINOIC ACID/HYALURONIC ACID 0.1%/0.1% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0541-2017

**Code Information:**

All Lots

<b>Product Description:</b> RETINOIC ACID SOLUTION in all strengths including 0.3%, 0.4%, 0.5%, 1%, RETINOIC ACID SOLUTION LIQUID, 0.4%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0542-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> SALICYLIC ACID SOLUTION in all strengths including 20%, 25%, 30%, and 40%, SALICYCLIC ACID 20%. 2.5%5-FU, SALICYCLIC ACID 20%, 5-FU 2.5% CREAM, SALICYCLIC ACID 20%/5-FU 2.5% MEDICATION STICK, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0543-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> TRICHLOROACETIC ACID SOLUTION in all strengths including: 10%, 12%, 15 %, 20%, 35%, 70%, and 85%, TRICHLOROCTIC ACID 10%/ LACTIC ACID 12%, TRICHLOROCTIC ACID 6%/LACTIC ACID 12%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0544-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> UREA 40% Cream, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0545-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> VITAMIN K OXIDE 5%, HQ 4%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0546-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> HYDROQUINONE CREAM in all strengths including 4%, 5%,6%, 7%, 8%, HYDROQUINONE 5%/KOJIC ACID 3% CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0547-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> HYDROQUINONE SOLUTION in all strengths including 4%, 28%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0548-2017 <b>Code Information:</b> All Lots
<b>Product Description:</b> LACTIC ACID SOLUTION in all strengths including 20%, 30%, and 60%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676 <b>Product Quantity:</b> <b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations. <b>Recall Number:</b> D-0549-2017

**Code Information:**

All Lots

**Product Description:**

ACNE SOLUTION (Salicylic acid 2%, Hydrocortisone 2%, Niacinamide 4%, Azelaic acid 2%, Clindamycin 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0550-2017

**Code Information:**

All Lots

**Product Description:**

BRIGHTENING CREAM (Retinoic acid 0.1%, Hydroquinone 4%, kojic acid 3%, hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0551-2017

**Code Information:**

All Lots

**Product Description:**

CALMING CREAM (Hydrocortisone 2.5%, Aloe vera powder), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0552-2017

**Code Information:**

All Lots

**Product Description:**

CLARIFYING CREAM (Retinoic acid 0.025%, Salicylic Acid 1%, Green tea powder, Ascorbic acid 2%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0553-2017

**Code Information:**

All Lots

**Product Description:**

CLEAR (Benzoyl Peroxide 3.75%, Clindamycin 1.2% Gel), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0554-2017

**Code Information:**

All Lots

**Product Description:**

CLEAR 2 (Benzoyl Peroxide 2.5%, Clindamycin 1.2% ), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0555-2017

**Code Information:**

All Lots

**Product Description:**

DUO Cream (Retinoic Acid 0.05%, Hydroquinone 6%, Kojic Acid 3%, Hydrocortisone 0.1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0556-2017

**Code Information:**

All Lots

**Product Description:**

FIRM AND FADE (Retinoic Acid 0.05%, Hydroquinone 6%, Kojic Acid 3%, Hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0557-2017

**Code Information:**

All Lots

**Product Description:**

GENERIC VI PEEL (Sal Acid 2%, TCA 7% Phenol 7%, Retinoic Acid 0.4%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0558-2017

**Code Information:**

All Lots

**Product Description:**

GENTLE BLEACHING CREAM (Retinoic Acid 0.025, Kojic Acid 3%, Hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0559-2017

**Code Information:**

All Lots

**Product Description:**

HI-LITE Cream (Retinoic Acid 0.05%, Hydroquinone 4%, Fluocinolone 0.01%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0560-2017

**Code Information:**

All Lots

**Product Description:**

JESSNERS PEEL (salicylic Acid 14% resorcinol 14%, Lactic acid 14%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0561-2017

**Code Information:**

All Lots

**Product Description:**

LP CREAM (Lidocaine 15%/Prilocaine 5%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0562-2017

**Code Information:**

All Lots

**Product Description:**

MALEK'S MAGIC (retinoic acid 0.05%, hydroquinone 6%, kojic acid 3%, hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0563-2017

**Code Information:**

All Lots

**Product Description:**

MALEK'S MAGIC PLUS (retinoic acid 0.1%, hydroquinone 6%, kojic acid 3%, hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0564-2017

**Code Information:**

All Lots

**Product Description:**

LTP (Lidocaine 10%, Tetracaine 2%, Phenylephrine 0.5%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0565-2017

**Code Information:**

All Lots

**Product Description:**

MODIFIED JESSNER PEEL (Sal Acid 14%, Lactic Acid 14%, glycolic 14%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0566-2017

**Code Information:**

All Lots

**Product Description:**

QUAD BLEACHING CREAM (retinoic acid 0.05%, hydroquinone 6%, kojic aid 3%, hydrocortisone 1%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0567-2017

**Code Information:**

All Lots

**Product Description:**

QUAD PEEL (Sal Acid 2%, TCA 7%, Phenol 7%, Retinoic acid 0.4%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0568-2017

**Code Information:**

All Lots

**Product Description:**

ROSACEA CREAM ( Metronidazole 1%, Niacinamide 4%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0569-2017

**Code Information:**

All Lots

**Product Description:**

REVERSE DML LOTION (Ketoconazole 2%, Metronidazole 2%, sulfacetamide sodium 10%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0570-2017

**Code Information:**

All Lots

**Product Description:**

SUPREME BLEACHING CREAM (Retinoic acid 0.05%, hydroquinone 6%, kojic acid 3%, Alpha Arbutin OTC 2%, Azeliac acid OTC 2%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0571-2017

**Code Information:**

All Lots

**Product Description:**

SUPREME CREAM (Retinoic acid 0.05%, hydroquinone 6%, kojic acid 3%, Alpha Arbutin otc 2%, Azeliac acid 2%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0572-2017

**Code Information:**

All Lots

**Product Description:**

TCA PEEL SOLUTION in all strengths including: 5%, 10%, 15%, 18%, and 20%, TCA 10%/LACTIC ACID 12%, TCA 6%/ LACTIC ACID12%, TCA 7%/SALICYLIC ACID 2% SOLUTION, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0573-2017

**Code Information:**

All Lots

**Product Description:**

TRI-BLEACHING CREAM (Retinoic Acid 0.05%, Hydroquinone 4%, Fluocinolone 0.01%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0574-2017

**Code Information:**

All Lots

**Product Description:**

TRI-BLEACHING CREAM (Retinoic Acid 0.1%, Hydroquinone 4%, Fluocinolone 0.01%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0575-2017

**Code Information:**

All Lots

**Product Description:**

TRI-BLEACHING CREAM HQ (retinoic Acid 0.05%, Hydroquinone 6%, Fluocinolone 0.01%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0576-2017

**Code Information:**

All Lots

**Product Description:**

ULTRA LITE CREAM (Hydroquinone 8%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0577-2017

**Code Information:**

All Lots

**Product Description:**

VI PEEL (Sal Acid 2%, TCA 17%, Phenol 7%, Retinoic Acid 0.4%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0578-2017

**Code Information:**

All Lots

**Product Description:**

TRI-BLEACHING CREAM (Retinoic Acid 0.05%, Hydroquinone 8%, Fluocinolone 0.01%), Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0579-2017

**Code Information:**

All Lots

**Product Description:**

DICLOFENAC 3% and 5% LIP BALM and DICLOFENAC 5% SPF 30 LIP BALM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0580-2017

**Code Information:**

All Lots

**Product Description:**

BETAMETHASONE 0.25%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676

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

Lack of Assurance of Sterility: There are also CGMP Deviations.

**Recall Number:**

D-0581-2017

<b>Code Information:</b> All Lots
<b>Product Description:</b> ENHANCED RETIN ANTI-WRINKLE CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0582-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> ENHANCED RETIN ANTI-WRINKLE CREAM, ENHANCED RETIN ANTI-WRINKLE CREAM 0.1%, ENHANCED RETIN 0.025% and 0.05%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0583-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> HCG in all strength including: 2,400, 9600,12,000 UNIT POWDER VIAL DROPS, HCG 11,000/B-12 UNITS SOLUTION, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0584-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> HUMAN CHORIONIC GONADOTROPIN in 300IU and 500 IU TABLETS, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0585-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> HYDROQUINONE CREAM in all strengths including: 4%, 5%, 6%, 7%, 8%,10%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0586-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> HYDROQUINONE 28% SOLUTION, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0587-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> TRETINOIN CREAM in all strengths including: 0.1%, 0.05%, TRETINOIN GEL in all strengths including 0.1% and 0.05%, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0588-2017
<b>Code Information:</b> All Lots
<b>Product Description:</b> TRETINOIN 0.02% IN OIL FREE CREAM, Rx only, Synergy RX, 4901 Morena Blvd # 504-A San Diego, CA 92117 (855) 792-6676
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility: There are also CGMP Deviations.
<b>Recall Number:</b> D-0589-2017