Enforcement Report - Week of February 5, 2020

Class II Drugs Event

Event ID:
84527

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/18/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MPRX, Inc. dba Medical Park Pharmacy
8230 Elmbrook Dr Ste 600b
Dallas TX United States

Distribution Pattern:
TX

Associated Products

Product Description:
DHEA/Pregnenol One 10.25 MG Cap

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0803-2020

Code Information:
Lot: L61406:42 Use by: 05/06/2020

Product Description:
Finasteride/Biotin 1 mg/50 mcg

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0804-2020

Code Information:
Lot: 60658:42 Use by: 12/28/2019

Product Description:
Lidocaine/Priloc/PE 15/5/0.25% 30 GM jars

Product Quantity:
2 jars

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0805-2020

Code Information:
Lot: 61367:42 Use by: 04/28/2020

Product Description:
Lidocaine/Priloc/PE 30/5/0.25% 30 GM jars

Product Quantity:
12 jars

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0806-2020

Code Information:
Lots: 61134:42 Use by: 01/31/2020; 61302:26 Use by: 04/14/2020; 61318:42 Use by: 04/19/2020

Product Description:
Liothyronine (T3) 80 mcg SR cap

Product Quantity:
5 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0807-2020

Code Information:
Lot: 61253:42 Use by: 04/01/2020

Product Description:
Liothyronine (T3) 92.5 MCG

Product Quantity:
4 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0808-2020

Code Information:
Lot: 61024:99 Use by: 02/20/2020

Product Description:
Magic Bullet Supplement

Product Quantity:
1 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0809-2020

Code Information:
Lot: 61048:99 Use by: 02/08/2020

Product Description:
Naltrexone 4.5 mg capsule

Product Quantity:
2 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0810-2020

Code Information:
Lot: 60564:42 Use by: 02/10/2020

Product Description:
Progesterone 200 mg Troche

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0811-2020

Code Information:
Lot: 61242:26 Use by: 02/28/2020

Product Description:
Progesterone 50 mg capsules

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0812-2020

Code Information:
Lot: 61215:26 Use by: 03/23/2020

Product Description:
Progesterone E4M SR 100 mg capsules

Product Quantity:
3 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0813-2020

Code Information:
Lot: 61219:42 Use by: 03/24/2020

Product Description:
Sildenafil 200 mg Troche (Clinic)

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0814-2020

Code Information:
Lot: 61392:42 Use by: 05/05/2020

Product Description:
Sildenafil 80 mg capsules

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0815-2020

Code Information:
Lot: 61404:42 Use by: 05/06/2020

Product Description:
Squaric Acid 0.1% Topical Solution (Clinic) 30 mL

Product Quantity:
1 bottle

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0816-2020

Code Information:
Lot: 61380:42 Use by: 05/04/2020

Product Description:
T3/T4 SR 9 mcg/38 mcg capsule

Product Quantity:
2 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0817-2020

Code Information:
Lot: 61296:42Use by: 04/13/2020

Product Description:
Tadalafil 20 mg Troche

Product Quantity:
9 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0818-2020

Code Information:
Lots: 61137:42 Use by: 03/08/2020; 61324:99 Use by: 04/04/2020; 60856:42 Use by: 02/02/2020

Product Description:
Tadalafil 6 mg Capsule

Product Quantity:
7 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0819-2020

Code Information:
Lots: 61229:26 Use by: 03/25/2020; 61229:42 Use by: 03/25/2020

Product Description:
Testosterone Topical Cream 4%

Product Quantity:
3 bottles

Reason for Recall:
Labeling: Incorrect or missing lot and/or expiration date. Products were compounded using expired components.

Recall Number:
D-0820-2020

Code Information:
Lot: 61463:42 Use by: 02/27/2020

Class II Drugs Event

Event ID:
84622

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
02/14/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/29/2020

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:
Prescriptions filled for patients in the following states: AK, AZ, CA, CO, DC, FL, IN, MA, MT, NC, NJ, NY, OR, SC, TX, UT, VA, WA, and WI.

Associated Products

Product Description:
Dimercaptopropanesulfonate Sodium (DMPS), Aqueous injection solution, 50mg/mL 5 mL SDV, Rx only, McGuff Compounding Pharmacy Services, Inc. Santa Ana, CA 92704

Product Quantity:

Reason for Recall:
Presence of Particulate Matter: Particulates observed in vials release for dispensing.

Recall Number:
D-0821-2020

Code Information:
Lot #18J1081, Exp 03/10/19

Class II Drugs Event

Event ID:
84712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/03/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville SC United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Nystatin Oral Suspension, USP 100,000 units per mL Cherry/Peppermint Flavor, 16 fl oz (473 mL) Rx Only, pai, Pharmaceutical Associates, Inc. Greenville, SC 29605. NDC 0121-0810-16

Product Quantity:
6288 16 oz bottles

Reason for Recall:
Subpotent: Out of specification for assay at the 12-month time point.

Recall Number:
D-0824-2020

Code Information:
Lots: BB70, BB71 Exp. May 2020

Class II Drugs Event

Event ID:
84757

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shandex Personal Care Manufacturing Inc.
5 Herriott St
Perth Canada

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Walgreens Acne Cleansing Bar, Benzoyl Peroxide 10%, NET WT 4 oz (113 g), 1 bar per carton, Distributed By: Walgreen Co., 200 Wilmot Road, Deerfield, IL 60015, NDC: 0363-0137-11

Product Quantity:
20448 cartons

Reason for Recall:
Presence of Foreign Substance; Metal contaminant visible in product (screen wire from manufacturing).

Recall Number:
D-0822-2020

Code Information:
Lot #: L 19173, Exp 06/20/2021

Class III Drugs Event

Event ID:
84749

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/31/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharma Usa Inc
666 Plainsboro Rd Bldg 200 Ste 230
Plainsboro NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Montelukast Sodium Chewable Tablets, 5 mg, 90-count bottles, Rx Only, Manufactured for : Macleods Pharma USA, Inc. Plainsboro, NJ Manufactured by: Macleods Pharmaceuticals Ltd Baddi, Himachal Pradesh, India NDC 33342-111-10

Product Quantity:
10680 units

Reason for Recall:
Failed Dissolution Specifications: testing revealed low out of specification result in one lot of product

Recall Number:
D-0823-2020

Code Information:
Lot #: BMD8901B, Exp. Date 02/2021