

# Enforcement Report - Week of April 22, 2020

## Class II Drugs Event

**Event ID:**

85183

**Product Type:**

Drugs

**Status:**

Ongoing

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

03/18/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/13/2020

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

Letter

**Recalling Firm:**

Aurobindo Pharma USA Inc.  
279 Princeton Hightstown Rd  
East Windsor NJ United States

**Distribution Pattern:**

Nationwide within the United States

## Associated Products

**Product Description:**

Acetaminophen and Codeine Phosphate Tablets, USP, 300 mg/15 mg, 100-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ 08810, NDC 13107-058-01

**Product Quantity:**

14194 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1229-2020

**Code Information:**

Lot #: 058180015A, 058180016A, Exp. Date 07/2021; 05818017B1, Exp. Date 09/2021

**Product Description:**

Acetaminophen and Codeine Phosphate Tablets, USP, 300 mg/30 mg, 100-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ 08810, NDC 13107-059-99

**Product Quantity:**

4332 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1230-2020

**Code Information:**

Lot #: 059180023A, 059180024A and 059180025A, Exp. Date 05/2021

**Product Description:**

Acetaminophen and Codeine Phosphate Tablets, USP, 300 mg/60 mg, 100-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., Dayton, NJ 08810, NDC 13107-060-01

**Product Quantity:**

57337 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1231-2020

**Code Information:**

Lot #: 060180017A, 060180019B1, 060180020A and 060180021A, Exp. Date 06/2021

**Product Description:**

Gabapentin Capsules, USP 100mg 1,000-count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc. Dayton, NJ 08810, NDC 65862-198-99

**Product Quantity:**

26625 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1232-2020

**Code Information:**

Lot #: 198180048A, Exp. Date 04/2021; 198180061A, Exp. Date 06/2020; 19819017A1, Exp. Date 02/2021

**Product Description:**

Levetiracetam Tablets USP 750 mg 120-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520, NDC 65862-247-08

**Product Quantity:**

8040 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1233-2020

**Code Information:**

Lot #: 24719001A1, Exp. Date 03/2021

**Product Description:**

Simvastatin Tablets, USP 40mg 90-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. Dayton, NJ 08810, NDC 65862-053-90

**Product Quantity:**

26976 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1234-2020

**Code Information:**

Lot #: 05319004A1, Exp. Date 03/2022

**Product Description:**Mirtazapine Tablets, USP 15mg, 30-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. Dayton, NJ 08810, NDC 13107-031-34  
NDC 65862-198-99**Product Quantity:**

56208 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1235-2020

**Code Information:**

Lot #: 031180028A, Exp. Date 03/2021

**Product Description:**Phentermine Hydrochloride Capsules, USP 15mg, 100-count bottles, Distributed by: Aurobindo Pharma USA, Inc. Dayton, NJ 08810, NDC 65862-053-90  
NDC 65862-198-99

**Product Quantity:**

2101 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1236-2020

**Code Information:**

Lot #: 105180004A, Exp. Date 03/2020

**Product Description:**

Oxycodone and Acetaminophen Tablets, USP 10 mg\*/325 mg 100-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. Dayton, NJ 08810, NDC 13107-046-01 NDC 65862-198-99

**Product Quantity:**

14707 units

**Reason for Recall:**

CGMP Deviations: Products were manufactured in a processing area in which water leakage was observed

**Recall Number:**

D-1237-2020

**Code Information:**

Lot #: 046180056A, Exp. Date 05/2020

## Class II Drugs Event

**Event ID:**

85274

**Product Type:**

Drugs

**Status:**

Ongoing

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

03/19/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/16/2020

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

Letter

**Recalling Firm:**Filltech USA, LLC  
380 Palmer Cir  
Rockwell NC United States**Distribution Pattern:**

USA Nationwide

## Associated Products

**Product Description:**

Dermatone (avobenzone, homosalate, octisalate, and octocrylene) Sunscreen Lotion Fragrance Free, SPF 30, package in 1.5 fl. oz. (44 mL) bottles, Distributed By: Beaumont Products, Inc. Kennesaw, GA 30144, UPC 020908422698

**Product Quantity:**

4919 bottles

**Reason for Recall:**

Microbial contamination of non-sterile products: positive test for yeast and bacteria.

**Recall Number:**

D-1241-2020

**Code Information:**

Lot #: 22J19, Exp 07/21

**Product Description:**

Dermatone (avobenzone, homosalate, octisalate, and octocrylene) Sunscreen Lotion Fragrance Free, SPF 50, packaged in a 1.5 fl. oz. (44 mL)

bottles, UPC: 087052727338; b) 2 FL. OZ. (59 mL) tubes, UPC: 08705272732; c) 4 FL. OZ. (118 mL) tubes, UPC: 087052727345, Distributed By: Beaumont Products, Inc. Kennesaw, GA 30144

**Product Quantity:**

4790 bottles; 20,403 tubes

**Reason for Recall:**

Microbial contamination of non-sterile products: positive test for yeast and bacteria.

**Recall Number:**

D-1242-2020

**Code Information:**

Lot #: a) 05J19, Exp 07/21; b) 05J19, Exp 07/21, 43L19, Exp 09/21; c) 43L19 Exp 09/21, 44L19 Exp 09/21

## Class II Drugs Event

**Event ID:**

85401

**Status:**

Ongoing

**Recall Initiation Date:**

04/03/2020

**Center Classification Date:**

04/13/2020

**Recalling Firm:**

Golden State Medical Supply Inc.  
5187 Camino Ruiz  
Camarillo CA 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:**

Losartan Potassium Tablets, USP, 25 mg, Rx only, a) 30 ct. (NDC 60429-316-30) b) 90ct. (NDC 60429-316-90) c) 1,000 ct. (60429-316-10) bottles, GSMS Incorporated, Manufactured by Arrow Pharm (Malta) Ltd., Packaged by GSMS Incorporated, Camarillo, CA 93012, USA

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

CGMP Deviations: Impurity for N-nitroso-N-methyl-4-aminobutyric Acid (NBMA) detected in active ingredient (API) used to manufacture finished products.

**Recall Number:**

D-1238-2020

**Code Information:**

Lot Code: GS018406, Exp. Date 6/30/2020; GS018858, Exp. Date 7/31/2020; GS019108, Exp. Date 7/31/2020; GS018521, Exp. Date 7/31/2020; GS018605, Exp. Date 7/31/2020; GS018911, Exp. Date 7/31/2020

## Class II Drugs Event

**Event ID:**

85404

**Status:**

Ongoing

**Recall Initiation Date:**

04/06/2020

**Product Type:**

Drugs

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

Voluntary: Firm initiated

**Center Classification Date:**

04/10/2020

**Initial Firm Notification of Consignee or Public:**  
Letter**Recalling Firm:**The Medicine Shoppe Pharmacy  
3524b Tamiami Trl  
Port Charlotte FL United States**Distribution Pattern:**

Florida

## Associated Products

**Product Description:**

Estriol Vaginal Cream (0.1%) 1 mg Cream 30 GM tubes, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

8 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1175-2020

**Code Information:**

Lot: 45036 Discard by: 7/31/2020; 45075 Discard by:8/7/2020

**Product Description:**

Testosterone W/Cosmetic HRT Base 100 MG (10%) Cream 30 GM, tubes Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

4 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1176-2020

**Code Information:**

Lot: 45027 Discard by: 07/27/2020

**Product Description:**

Fluorouracil (5-FU) 4.5% Cream 100 GM, tube Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1177-2020

**Code Information:**

Lot: 45044 Discard by: 8/2/2020

**Product Description:**

Bi-Est8:2/Progesterone/Testosterone 1.0/50 MG/.5MG/ML Cream 30 GM tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

2 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1178-2020

**Code Information:**

Lot: 44767 Discard by: 5/17/2020

**Product Description:**

Bi-Est8:2/Progesterone/Testosterone 1.0/50 MG/.5MG/ML Cream 30 GM, tube Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1179-2020

**Code Information:**

Lot: 44639 Discard by: 11/28/2020

**Product Description:**

Naltrexone (Loxoral) 4.5 mg Capsules, 60 count bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1180-2020

**Code Information:**

Lot: 44898 Discard by: 3/23/2020

**Product Description:**

Estradiol/Progesterone/Testosterone 1.5/100/1.25 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1181-2020

**Code Information:**

Lot: 44560 Discard by: 03/24/2020

**Product Description:**

Estradiol Vag Cream 0.01% Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

7 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1182-2020

**Code Information:**

Lot: 44967 Discard by: 7/10/2020; 45171 Discard by: 9/2/2020

**Product Description:**

Testosterone w/ Atravis 20 mg (2%) Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1183-2020

**Code Information:**

Lot: 44965 Discard by: 7/10/2020

**Product Description:**

Testosterone w/ Atravis 100 mg/mL GEL, 90 gm pump, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

3 bottles

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1184-2020

**Code Information:**

Lot: 45114 Discard by: 08/20/2020; 45139 Discard by: 8/27/2020

**Product Description:**

Estradiol 1.8 mg capsule 30 cap bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1185-2020

**Code Information:**

Lot: 45073 Discard by: 8/7/2020

**Product Description:**

Bi-Est (1:1) Progest/Test 0.5 mg/40 mg/10.5 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1186-2020

**Code Information:**

Lot: 44894 Discard by: 6/15/2020

**Product Description:**

Bi-Est (8:2) Progest/Test 2/80/3 mg/mL cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1187-2020

**Code Information:**

Lot: 45098 Discard by: 8/16/2020

**Product Description:**

Bi-Est (1:1) Progest/Test 0.5 mg/1.5 mg/mL cream 60 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1188-2020

**Code Information:**

Lot: 45100 Discard by: 8/16/2020

**Product Description:**

Bi-Est (1:1) Progesterone/Testost 1.0 mg/60 mg/0.5 mg/mL Cream 60 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1189-2020

**Code Information:**

Lot: 45116 Discard by: 8/22/2020

**Product Description:**

Progesterone/Versa Base 20 mg (2%) Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1190-2020

**Code Information:**

Lot: 45104 Discard by: 8/18/2020

**Product Description:**

Progesterone 200 mg Capsules 90 capsules, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

3 bottles

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1191-2020

**Code Information:**

Lot: 45106 Discard by: 8/16/2020; 45128 Discard by: 8/25/2020; 45227 Discard by: 9/14/2020

**Product Description:**

Bi-Est 1:1/Progesterone/Testosterone 1mg/40 mg/0.5 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1192-2020

**Code Information:**

Lot: 45108 Discard by: 8/18/2020

**Product Description:**

Bi-Est (8:2)/DHEA/Testosterone 0.8 mg/ 9/0.4 mg/0.2 mg/mL Cream 6 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1193-2020



**Code Information:**

Lot: 44798 Discard by: 5/22/2020

**Product Description:**

Hydroquinone/Fluocinolone/Tretinoin/Kojic Acid 4/0.01/0.05/2% Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1194-2020

**Code Information:**

Lot: 45077 Discard by: 3/12/2020

**Product Description:**

Ergotamine Tartrate 1 mg/Caffeine 100 mg Base Suppository (Pink) 48 count box, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 box

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1195-2020

**Code Information:**

Lot: 45247 Discard by: 9/19/2020

**Product Description:**

Diethylstilbestrol 1 mg capsule 300 capsules bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1196-2020

**Code Information:**

Lot: 45102 Discard by: 8/17/2020

**Product Description:**

Bi-Est 8:2/Progesterone 2.5 mg/150/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1197-2020

**Code Information:**

Lot: 44908 Discard by: 6/17/2020

**Product Description:**

Bi-Est 8:2/Progesterone/Testosterone DHEA 4.0/100/1/25.0 mg capsules 90 capsules bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1198-2020

**Code Information:**

Lot: 45130 Discard by: 8/25/2020

**Product Description:**

Bi-Est 1:1/Progesterone/Testosterone 2.0/100/0.25 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

2 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1199-2020

**Code Information:**

Lot: 45023 Discard by: 7/27/2020; 45268 Discard by: 9/27/2020

**Product Description:**

Bi-Est 1:1/Progest/DHEA 1/40/5 mg/mL Cream 30 mL jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1200-2020

**Code Information:**

Lot: 45146 Discard by: 8/30/2020

**Product Description:**

Bi-Est 1:1/Progest/DHEA 0.5 mg/180 mg/25 mg/mL Cream 30 mL jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1201-2020

**Code Information:**

Lot: 44850 Discard by: 6/4/2020

**Product Description:**

Bi-Est (8:2)/Progest/Test/DHEA 6/50/0.5/10 mg/mL Cream 30 mL, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1202-2020

**Code Information:**

Lot: 45148 Discard by: 8/30/2020

**Product Description:**

Bi-Est (50/50)/Progesterone 1.25 mg/80 mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

2 tubes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1203-2020

**Code Information:**

Lot: 45006 Discard by: 7/18/2020; 45251 Discard by: 9/22/2020

**Product Description:**

Testosterone in Atrevis 50 mg/mL Gel 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1204-2020

**Code Information:**

Lot: 44488 Discard by: 8/22/2020

**Product Description:**

Paregoric Compound (contains Morphine) Solution 480 mL bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1205-2020

**Code Information:**

Lot: 45161 Discard by: 5/4/2020

**Product Description:**

Hydromorphone Oral 1 mg/mL Solution 240 mL, bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1206-2020

**Code Information:**

Lot: 45163 Discard by: 9/1/2020

**Product Description:**

Clobetasol Mouth Rinse 0.05% Solution 450 mL bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1207-2020

**Code Information:**

Lot: 45169 Discard by: 9/2/2020

**Product Description:**

Naltrexone 4.5 mg/mL Suspension 30 mL bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1208-2020

**Code Information:**

Lot: 45177 Discard by: 9/4/2020

**Product Description:**

Estriol 5 mg Suppository 36 each box, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 box

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1209-2020

**Code Information:**

Lot: 45179 Discard by: 9/5/2020

**Product Description:**

Hydrocortisone in Aquaphor/Therapeutic Moisturizing Cream 100 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1210-2020

**Code Information:**

Lot: 45211 Discard by: 9/9/2020

**Product Description:**

Hydrocortisone 2.5%/Econazole 1% 50/50 Using Powder 25%/1% Cream 60 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1211-2020

**Code Information:**

Lot: 45212 Discard by: 9/9/2020

**Product Description:**

Bi-Est (1:1)/Progesterone/Testosterone 2.0 mg/40 mg/1.0 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1212-2020

**Code Information:**

Lot: 44892 Discard by: 4/15/2020

**Product Description:**

Bi-Est (50/50)/Progesterone/Testosterone 1.5 mg/40 mg/0.5 mg/mL Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1213-2020

**Code Information:**

Lot: 44840 Discard by: 6/1/2020

**Product Description:**

Bi-Est (50/50)/Progesterone/Testost 1.5/100/0.5 mg Cream 30 gm tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1214-2020

**Code Information:**

Lot: 45132 Discard by: 8/26/2020

**Product Description:**

Bi-Est (8:2)/Progesterone 2/100 mg/mL capsule 90 caps bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1215-2020

**Code Information:**

Lot: 45239 Discard by: 9/16/2020

**Product Description:**

Bi-Est (50/50)/Progesterone 0.2 mg/70 mg Cream 30 gm jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1216-2020

**Code Information:**

Lot: 45110 Discard by: 8/20/2020

**Product Description:**

Bi-Est (1:1)/Progesterone/Testosterone 2.5/150/1.5 mg/mL Versabase CR 90 mL bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1217-2020

**Code Information:**

Lot: 45280 Discard by: 9/23/2020

**Product Description:**

Bi-Est (8:2)/Progesterone/Testosterone 0.5/75 mg per 0.2 mL Cream 6 mL jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1218-2020

**Code Information:**

Lot: 44518 Discard by: 3/15/2020

**Product Description:**

Estriol/Testosterone Vaginal 0.1/0.1% Cream 30 gm jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1219-2020

**Code Information:**

Lot: 45221 Discard by: 9/12/2020

**Product Description:**

Paregoric Alternate Elixir 300 mL bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1220-2020

**Code Information:**

Lot: 45231 Discard by: 6/16/2020

**Product Description:**

Progesterone/Natacream 20 mg/2% mL Cream 60 gm jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1221-2020

**Code Information:**

Lot: 45233 Discard by: 9/15/2020

**Product Description:**

Testosterone in Atrevis 75 mg/mL Gel 90 GMS tube, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 tube

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1222-2020

**Code Information:**

Lot: 45235 Discard by: 9/15/2020

**Product Description:**

Ketoprofen/DMSO 20%/10% Lipoderm 50 gm jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1223-2020

**Code Information:**

Lot: 44552 Discard by: 3/23/2020

**Product Description:**

Testosterone w/Cosmetic HRT Base 20 mg (2%) Cream 30 GM jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1224-2020

**Code Information:**

Unknown

**Product Description:**

Tretinoin 0.1% in Versabase Cream 0.1% Versabase CR 45 gm jar, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 jar

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1225-2020

**Code Information:**

Lot: 45240 Discard by: 6/18/2020

**Product Description:**

Ergotamine Tartrate 1 mg/Caffeine 100 mg base F Suppository (Pink) 48 suppositories, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

2 boxes

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1226-2020

**Code Information:**

Lot: 45247 Discard by: 9/19/2020

**Product Description:**

Betahistine 16 mg Capsule 180 capsules bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

2 bottles

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1227-2020

**Code Information:**

Lot: 45266 Discard by: 9/26/2020

**Product Description:**

Levothyroxin (T4)/Liothyronine (T3) SR 130 mg/175 mg capsule 21 capsules bottle, Rx, The Medicine Shoppe Pharmacy, Port Charlotte, FL

**Product Quantity:**

1 bottle

**Reason for Recall:**

Lack of Processing Control

**Recall Number:**

D-1228-2020

**Code Information:**

Lot: 45274 Discard by: 9/27/2020

## Class II Drugs Event

**Event ID:**

85440

**Status:**

Ongoing

**Recall Initiation Date:**

04/14/2020

**Center Classification Date:**

04/16/2020

**Recalling Firm:**B & B Pharmaceuticals, Inc.  
8591 Prairie Trail Dr Ste C600  
Englewood CO United States**Distribution Pattern:**

USA Nationwide

**Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Estradiol, USP (Non-Micronized) (Hemihydrate), packaged in: a) 500 grams (NDC 63275-9900-8), b) 100 grams (NDC 63275-9900-5), c) 25 grams (NDC 63275-9900-4), Distributed by B&amp;B Pharmaceuticals, Inc. 800-499-3100

**Product Quantity:**

3,825 grams

**Reason for Recall:**

cGMP deviations: Presence of foreign material (Teflon)introduced at the production level.

**Recall Number:**

D-1244-2020

**Code Information:**

Lot #: 18K26-BB02-PR00553, Reassay 10/09/2023 Product # 700365, 700362 &amp; 700363

## Class II Drugs Event

**Event ID:**

85482

**Status:**

Ongoing

**Recall Initiation Date:**

04/15/2020

**Center Classification Date:**

04/16/2020

**Recalling Firm:**

H J Harkins Company Inc dba Pharma Pac

**Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Letter



1400 W Grand Ave Ste F  
Grover Beach CA United States

**Distribution Pattern:**

Product was distributed in CA and AZ.

## Associated Products

**Product Description:**

Acetaminophen and Codeine Phosphate 300/30 mg tablet, packaged in: a) 10-count bottle (NDC 52959-0003-10), b) 12-count bottle (NDC 52959-0003-12), c) 14-count bottle (NDC 52959-0003-14), d) 15-count bottle (NDC 52959-0003-15), e) 16-count bottle (NDC 52959-0003-16), f) 20-count bottle (NDC 52959-0003-20), g) 30-count bottle (NDC 52959-0003-30), h) 60-count bottle (NDC 52959-0003-60), Rx Only, Mfg. Aurobindo; Repack: H.J. Harkins Co., Inc., Grover Beach, CA 93433

**Product Quantity:**

9,000 tablets

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-1246-2020

**Code Information:**

Lot # ATP12ZT, Exp. 05/21