Enforcement Report - Week of October 14, 2020

Class II Drugs Event

Event ID:
86442

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Calvin Scott & Company, Inc.
209 Eubank Blvd Ne
Albuquerque NM United States

Distribution Pattern:
Repacked drug products distributed to 12 physician consignees located in the following states: CA, ID, IL,OK, RI

Associated Products

Product Description:
Diethylpropion, 25 mg tablets, Rx only, Distributed by: Calvin Scott & Co. Inc. Albuquerque, NM 87123; MFG. Lannett Company, Philadelphia, PA 19136, NDC 00527-1475-01

Product Quantity:

Reason for Recall:
cMGP Deviations: Drug products repackaged into pouches without supporting stability studies.

Recall Number:
D-0009-2021

Code Information:
Lot #: CS19311, CS19337, Exp 12/20; CS20018B, CS20019, CS20037, CS20075, CS20076, CS20112, CS20169, Exp 8/21; CS20168, Exp 12/21; CS20199, Exp 5/22; CS20243, Exp 7/22

Product Description:
Diethylpropion, 75 mg tablets, Rx only, Distributed by: Calvin Scott & Co. Inc. Albuquerque, NM 87123; MFG. Lannett Company, Philadelphia, PA 19136, NDC 00527-1477-01

Product Quantity:

Reason for Recall:
cMGP Deviations: Drug products repackaged into pouches without supporting stability studies.

Recall Number:
D-0010-2021

Code Information:
Lot #: CS19192, CS19226, CS19263, Exp 10/20; CS19300, Exp 7/21; CS19338, Exp 8/21; CS20034, Exp 10/21; CS20077, Exp 1/22, CS20165, CS20241, Exp 4/22

Product Description:
Phentermine, 30 mg capsules, Rx only, Distributed by: Calvin Scott & Co. Inc. Albuquerque, NM 87123; MFG. Lannett Company, Philadelphia, PA 19136, NDC 00527-0597-10

Product Quantity:

Reason for Recall:
cMGP Deviations: Drug products repackaged into pouches without supporting stability studies.

Recall Number:
D-0011-2021

Code Information:
Lot #: CS19309, CS20098, Exp 12/21

Class II Drugs Event

Event ID:
86498

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/15/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
FL, GA

Associated Products

Product Description:
Ranitidine 150 mg, a) 60 Tabs (NDC 61919-339-60); and b) 90 Tabs (NDC 61919-339-90) bottles, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534

Product Quantity:
a) 54 bottles; b) 26 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0016-2021

Code Information:
Lots: a) 09AU1911 Exp. 02/28/2022; b) 09SE1904 Exp. 03/31/2022

Product Description:
Ranitidine 300 mg, 30 Tabs bottles, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 NDC 61919-455-30

Product Quantity:
26 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0017-2021

Code Information:
Lot: 29JA1915 Exp. 09/30/2021

Class II Drugs Event

Event ID:
86499

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/30/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
GA

Associated Products

Product Description:
Losartan Potassium 100 mg, 30 Tabs bottles, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 NDC 61919-952-30

Product Quantity:
33 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-MethylNitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level per manufacturer

Recall Number:
D-0018-2021

Code Information:
Lot: 27AU1801 Exp. 02/28/2021

Class II Drugs Event

Event ID:
86533

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/02/2020

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
AZ, OK

Associated Products

Product Description:
Nature-Throid 1 GR (65 mg), Each Tablet Contains: Thyroid USP 1 GR (65 mg), Liothyronine (T3) 9 mcg, Levothyroxine (T4) 38 mcg, 100 Tablets per bottle, Rx Only, Pkg By PD-Rx Pharmaceuticals Incorporated, Oklahoma City, OK 73127, NDC 43063-819-01.

Product Quantity:
20 bottles

Reason for Recall:
CGMP deviations; repackaged product was recalled by the manufacturer because it was manufactured under the same conditions as products found to be sub-potent.

Recall Number:
D-0005-2021

Code Information:
Lot #: J18C68 Exp. 10/31/20

Class III Drugs Event

Event ID:
86409

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PAI Holdings, LLC. dba Pharmaceutical Associates Inc
1700 Perimeter Rd
Greenville SC United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Citalopram Oral Solution, USP 20 mg/10 mL, 10 mL unit dose cups, Rx Only, Mfg for: Pharmaceutical Associates, Inc. Greenville, SC 29605 NDC 0121-1696-40

Product Quantity:
13480 cups

Reason for Recall:
Failed Impurities/Degradation Specifications; high out of specification results obtained at the 9 month stability timepoint

Recall Number:
D-0015-2021

Code Information:
Lots: C1EE Exp. 04/2021, BD82 Exp. 11/2020, BD83 Exp. 11/2020, C16D Exp. 02/2021, C563 Exp. 11/2021, C574 Exp. 11/2021

Class III Drugs Event

Event ID:
86486

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States

Distribution Pattern:
Distributed Nationwide in the USA including Puerto Rico

Associated Products

Product Description:
NYSTATIN ORAL SUSPENSION, USP 100,000 units per mL Contains: Alcohol 0.5% v/v (Bubblegum Flavored) 16 fl. oz. (480 mL) Manufactured by: VistaPharm, Inc. Largo FL 33771, USA NDC 66689-008-16 UPC 6668900816,

Product Quantity:
14,244 16 oz bottles

Reason for Recall:
Failed Impurties/Degradation Specifications: out of specification results for an impurity for one lot

Recall Number:
D-0019-2021

Code Information:
Lots: 638800 Exp 10/21