Enforcement Report - Week of September 25, 2019

Class II Drugs Event

Event ID:
83538

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/09/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/13/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Ridge Properties, LLC
4995 Ridge Dr NE
Salem OR United States

Distribution Pattern:
Nationwide in the USA via internet sales through Amazon.com; ebay.com; Walmart.com; tatbalm.net; Naturallyhl.com

Associated Products

Product Description:
PRE-TAT (lidocaine) 3 in 1 Pre Tattoo Prep With Lidocaine Cream, 4%, packaged in a) 1 OZ (NDC 69804-002-05), b) 2 OZ (NDC 69804-002-02), and c) 4 OZ (NDC 69804-002-03) jars, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
383.65 ounces total

Reason for Recall:
Microbial Contamination of Non-Sterile Products: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1856-2019

Code Information:
Lot # 1222, Exp 06/14/2023

Product Description:
PRE-TAT (lidocaine) 3 in 1 Pre Tattoo Prep With Lidocaine Liquid Gel, 4%, packaged in a) 1 Oz (NDC 69804-019-14), b) 2 Oz (NDC 69804-019-15), and c) 4 Oz (NDC 69804-019-16) bottles, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
109.64 ounces total

Reason for Recall:
Microbial Contamination of Non-Sterile Products: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1857-2019

Code Information:
Lot # 1213, Exp 06/05/2023

Product Description:
Superior Pain & Itch Relief (lidocaine) Cream, 4%, packaged in a) 1 OZ (NDC 69804-070-05), b) 2 OZ (NDC 69804-070-02), and c) 4 OZ (NDC 69804-070-03) jars, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
383.65 ounces total

Reason for Recall:
Superpotent Drug: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1858-2019

Code Information:
Lot # 1222, Exp 06/14/2023

Product Description:
Superior Pain & Itch Relief (lidocaine) Liquid Gel, 4%, packaged in a) 1 Oz (NDC 69804-073-14), b) 2 Oz (NDC 69804-073-15), and c) 4 Oz (NDC 69804-073-16) bottles, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
109.64 ounces total

Reason for Recall:
Superpotent Drug: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1859-2019

Code Information:
Lot # 1213, Exp 06/05/2023

Product Description:
Soothing Sore Relief (lidocaine) Cream, 4%, packaged in a) 1 OZ (NDC 69804-074-05), b) 2 OZ (NDC 69804-074-02), and c) 4 OZ (NDC 69804-074-03) jars, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
136 ounces

Reason for Recall:
Superpotent Drug: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1860-2019

Code Information:
Lot # 1228, Exp 06/21/2023

Product Description:
Soothing Sore Relief (lidocaine) Liquid Gel, 4%, packaged in a) 1 Oz (NDC 69804-077-14), b) 2 Oz (NDC 69804-077-15), and c) 4 Oz (NDC 69804-077-16) bottles, OTC, Manufactured, packed & distributed by Pain Relief Naturally, Salem, OR 97301.

Product Quantity:
104.1 ounces

Reason for Recall:
Superpotent Drug: products were found to be contaminated and above specification for lidocaine assay.

Recall Number:
D-1861-2019

Code Information:
Lot # 1135, Exp 12/27/2022

Class II Drugs Event

Event ID:
83581

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurolife Pharma, LLC

2400 US Highway 130
Dayton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fexofenadine Hydrochrloride Tablets USP, 180 mg, 100-count bottle, Distributed by: Aurohealth LLC., 2572 Brunswick Pike, Lawrenceville, NJ 08648, NDC 58602-711-21

Product Quantity:
8,240 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1864-2019

Code Information:
Lot #: 067180008A, Exp 03/21

Product Description:
Allergy Relief (Fexofenadine Hydrochrloride) Tablets USP, 180 mg, packaged in a) 15-count cartons (NDC 60000-409-53); b) 30-count cartons (NDC 60000-409-30); c) 45-count bonus cartons (NDC 60000-409-48); d) 45-count cartons (NDC 60000-409-45); CAREone, Distributed by: Foodhold U.S.A., LLC, Landover, MD 20785.

Product Quantity:
a) 9662 cartons; b) 7382 cartons; c) 5184 cartons; d) 9842 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1865-2019

Code Information:
Lot #s: a) 067180025D1, Exp 07/21; b) 067180025B1, Exp 07/21; c) 067180025A1, Exp 07/21; d) 067180025C1, Exp 07/21

Product Description:
Allergy Relief (fexofenadine hydrochrloride) tablets, 180 mg, 5-count carton, Good Neighbor Pharmacy, Distributed By Amerisource Bergen, 1300 Morris Drive, Chesterbrook, PA 19087, NDC 46122-387-23.

Product Quantity:
3240 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1866-2019

Code Information:
Lot #: 067180024A1, Exp 07/21

Product Description:
fexofenadine hydrochloride tablets USP, 180 mg, 150-count bottle, Member's Mark, Distributed by: Sam's West, Inc., Bentonville, AR 22716, NDC 68196-976-91, UPC 0 78742 23550 9.

Product Quantity:
71,748 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1867-2019

Code Information:
Lot #'s: 067180009A, Exp 03/21; 067180013A, 067180014A, 067180015A, Exp 04/21; 067180018A, Exp 05/21; 067180020A, Exp 06/21; 067180021A1, 067180022A1, Exp 07/21; 06718028A1, 06718028B1, Exp 09/21; 06719001A3, Exp 01/22

Product Description:
Fexofenadine Hydrochloride Tablets USP, 180 mg, packaged in a) 30-count carton (NDC 70677-0008-2) and b) 15-count carton (NDC 70677-0008-1), sunmark, Distributed by McKesson, One Post Street, San Francisco, CA 94104.

Product Quantity:
a) 11,928 cartons; b) 288 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1868-2019

Code Information:
Lot #s: a) 067180016B, Exp 05/21 and b) 067180024F1, Exp 07/21

Product Description:
Allergy Relief (Fexofenadine HCl) tablets USP, 180 mg, 15-count cartons, equate, Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC 49035-995-62.

Product Quantity:
129,600 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1869-2019

Code Information:
Lot #s: 067180010A, Exp 03/21; 067180023C1, 067180024D1, Exp 07/21

Product Description:
Fexofenadine Hydrochloride Tablets USP, 180 mg, packaged in a) 15-count cartons (NDC 62011-0315-1); and b) 30-count cartons (NDC 62011-0315-2) HealthMart PHARMACY, Distributed by McKesson, One Post Street, San Francisco, CA 94104.

Product Quantity:
a) 10,992 cartons; b) 24,792 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1870-2019

Code Information:
Lot #s: a) 067180010B, Exp 03/21; 067180024E1, Exp 07/21; b) 067180016A, Exp 05/21

Product Description:
Fexofenadine HCL Tablets USP, 180 mg, 500's BRITE STOCK; Manufactured for: Aurohealth LLC., 2572 Brunswick Pike, Lawrenceville, NJ 08648; Manufactured by: Aurolife Pharma LLC, Dayton, NJ 08810.

Product Quantity:
6104 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1871-2019

Code Information:
Lot #s:067180011A, 067180012A, Exp 04/21, 06718027B1, Exp 09/21

Product Description:
Allergy (Fexofenadine Hydrochloride) Tablets USP, 180 mg, 30-count bottles, Distributed by: Aurohealth LLC, 2572 Brunswick Pike, Lawrenceville, NJ 08648; NDC 58602-820-09.

Product Quantity:
240 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1872-2019

Code Information:
Lot #: 067180026A1, Exp 07/21

Product Description:
Wal-Fex (Fexofenadine Hydrochloride) Tablets USP, 180 mg, 5-count cartons, Distributed By: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-0097-55.

Product Quantity:
4920 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1873-2019

Code Information:
Lot #: 06718027A1, Exp 09/21

Product Description:
Allergy (Fexofenadine Hydrochloride) Tablets USP, 180 mg, 30-count cartons, DISCOUNT drug mart FOOD FAIR, Distributed by: Discount Drug Mart, 211 Commerce Drive, Medina, OH 44256, NDC 53943-021-09.

Product Quantity:
4536 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-1874-2019

Code Information:
Lot #: 067180024B1, Exp 07/21

Class II Drugs Event

Event ID:
83698

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/09/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus OH United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Oxcarbazepine Oral Suspension, USP, 300 mg/5 mL, 250 mL per bottle, Rx Only, Distr. by: West-Ward Pharmaceuticals,Eatontown, NJ. NDC:0054-0199-59

Product Quantity:
32,347 bottles

Reason for Recall:
Failed Impurities/Degradation Specificattion

Recall Number:
D-1863-2019

Code Information:
Lot, expiry: Lots AA3957A, AA3958A, exp May 2020; Lot AA5164A, exp Sep 2020

Class II Drugs Event

Event ID:
83733

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/06/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Anagrelide Capsules, USP, 0.5 mg, 100-count bottle, Rx only, Manufactured in India for: Torrent Pharma Inc., Basking Ridge, NJ 07920, NDC 13668-453-01.

Product Quantity:
2472 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: High Out Of Specification results for impurities detected during routine stability testing.

Recall Number:
D-1862-2019

Code Information:
Lot #: BFE2E003, Exp 08/31/2020