# Enforcement Report - Week of November 29, 2017

## Class II Drugs Event

**Event ID:**
78170

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/11/2017

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

**Center Classification Date:**
11/19/2017

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

**Recalling Firm:**
United Therapeutics Corp.
55 Tw Alexander Dr
Durham NC United States

**Distribution Pattern:**
PA

### Associated Products

**Product Description:**
TYVASO (treprostinil) Inhalation Solution Treprostinil 1.74 mg/2.9 mL (0.6 mg/mL) Tyvaso Inhalation System Starter Kit Model# TD-100/A, Rx Only, Manufactured by United Therapeutics Corporation Research Triangle Park, NC 27709, NDC# 6630220601

**Product Quantity:**
12 devices

**Reason for Recall:**
CGMP Deviations

**Recall Number:**
D-0083-2018

**Code Information:**
Lot #: 2101152; Exp. 12/11/2017 Lot #: 2101195; Exp. 04/26/2019

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## Class II Drugs Event

**Event ID:**
78257

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
08/22/2017

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

**Center Classification Date:**
11/19/2017

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

**Recalling Firm:**
Shata Trading, Inc.
4 19th St
Brooklyn NY United States

**Distribution Pattern:**
NY

### Associated Products

**Product Description:**
No. 1 Faiza Beauty Cream Manufactured by: Poonia Brothers (Pak), Gujranwala, Distributed by Shata Traders Inc., 4, 19th Street, Brooklyn, NY 11232. UPC 5842109854239

**Product Quantity:**
96 foil packages

**Reason for Recall:**
Marketed Without an Approved NDA/ANDA

**Recall Number:**
D-0084-2018

**Code Information:**
Batch # 16L63 Lot # 223190

## Class II Drugs Event

**Event ID:**
78462

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/03/2017

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

**Center Classification Date:**
11/21/2017

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

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

**Distribution Pattern:**
Product distributed throughout United States.

## Associated Products

**Product Description:**
Extra Strength Naturally HL Bed Sore Relief Cream with Added Lidocaine, (lidocaine HCL 4%), 1/2 oz Balm(NDC 69804-008-06), 1 oz Balm (NDC 69804-008-05), 2 oz Balm(NDC 69804-008-02), and 4 oz Balm(NDC 69804-008-03), Manufactured by Pain Relief Naturally, www.Naturally HL.com

**Product Quantity:**

**Reason for Recall:**
GMP Deviations: inadequate manufacturing control processes

**Recall Number:**
D-0086-2018

**Code Information:**
All batches and lots, exp 10/17/2018. Not all batches were assigned lot numbers

**Product Description:**
Extra Strength PreTAT by TAT BALM Gel, (lidocaine HCL 4%), 1/2 oz Gel (NDC 69804-018-09), 1 oz Gel (NDC 69804-018-10) , 2 oz Gel (NDC 69804-018-11), and 4 oz Gel (NDC 69804-018-12) jars, Manufactured by Pain Relief Naturally, www.Naturally HL.com

**Product Quantity:**

**Reason for Recall:**
GMP Deviations: inadequate manufacturing control processes

**Recall Number:**
D-0087-2018

**Code Information:**
All batches and lots, exp 10/17/2018. Not all batches were assigned lot numbers

**Product Description:**
Extra Strength Naturally HL Hemorrhoid Numbing Spray with Lidocaine, (lidocaine HCL 4%), 1/2 oz Spray (NDC 69804-015-08), 1 oz Spray (NDC 69804-015-07), 2 oz Spray (NDC 69804-015-01) and 4 oz Spray (NDC 69804-015-04) bottles, Manufactured by Pain Relief Naturally, www.Naturally HL.com

**Product Quantity:**

**Reason for Recall:**
GMP Deviations: inadequate manufacturing control processes

**Recall Number:**
D-0088-2018

**Code Information:**
All batches and lots, exp 10/17/2018. Not all batches were assigned lot numbers

**Product Description:**
Extra Strength Naturally HL Liquid Hemorrhoid Relief Gel, (lidocaine HCL 4%), 1/2 oz Liquid Gel (NDC 69804-024-13), 1 oz Liquid Gel (NDC 69804-024-14), 2 oz Liquid Gel (NDC 69804-024-15), 4 oz Liquid Gel (NDC 69804-024-16) bottles, Manufactured by Pain Relief Naturally, www.Naturally HL.com

**Product Quantity:**

**Reason for Recall:**
GMP Deviations: inadequate manufacturing control processes

**Recall Number:**
D-0089-2018

**Code Information:**
All batches and lots, exp 10/17/2018. Not all batches were assigned lot numbers

**Product Description:**
Extra Strength Naturally HL Hemorrhoid Numbing with Lidocaine, (lidocaine HCL 4%), 1/2 oz Balm (NDC 69804-014-06), and 2 oz Balm(NDC 69804-014-03), Manufactured by Pain Relief Naturally, www.Naturally HL.com

**Product Quantity:**

**Reason for Recall:**
GMP Deviations: inadequate manufacturing control processes

**Recall Number:**
D-0090-2018

**Code Information:**
All batches and lots, exp 10/17/2018. Not all batches were assigned lot numbers

## Class II Drugs Event

**Event ID:**
78471

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/28/2017

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

**Center Classification Date:**
11/20/2017

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

**Recalling Firm:**
Leading Pharma, LLC
3 Oak Rd
Fairfield NJ United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Lorazepam Tablets, USP CIV, 0.5 mg, 500-count bottle, Rx Only, Manufactured by: Leading Pharma, LLC Fairfield, NJ 07004 NDC 69315-904-05

**Product Quantity:**
2952 500-count bottles

**Reason for Recall:**
Labeling: Label Error on Declared Strength. Bottle labeled as 0.5 mg tablets contained 1mg tablets of lorazepam

**Recall Number:**
D-0085-2018

**Code Information:**
Lot #E00717

## Class II Drugs Event

**Event ID:**
78490

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/24/2017

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

**Center Classification Date:**
11/21/2017

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

**Recalling Firm:**
Amerisource Health Services
2550 John Glenn Ave Ste A
Columbus OH United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Paroxetine Tablets, USP, 30mg, 100 tablets (10 x 10) , Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Columbus, Ohio 43217, NDC 68084-046-01

**Product Quantity:**
74 cartons (cartons of 100 individual unit doses)

**Reason for Recall:**
Presence of Foreign Tablets/Capsules.

**Recall Number:**
D-0091-2018

**Code Information:**
Lot 172291

## Class II Drugs Event

**Event ID:**
78566

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/17/2017

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

**Center Classification Date:**
11/21/2017

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

**Recalling Firm:**
Lupin Limited
15 - B I Phase 1a I D C Verna Industrial Road
Vasco Da Gama India

**Distribution Pattern:**
Product was distributed throughout the United States, including Puerto Rico.

## Associated Products

**Product Description:**
Pravastatin Sodium USP, tablets, 40 mg, 90-count bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, NDC 68180-487-09

**Product Quantity:**

**Reason for Recall:**
Presence of foreign tablets/capsules: This product lot is being recalled due to a pharmacy complaint where one Duloxetine Delayed Release Capsule, 30mg was found in a Pravastatin Sodium Tablets USP, 40mg bottle.

**Recall Number:**
D-0092-2018

**Code Information:**
Lot # G702459, Exp 2/20

## Class III Drugs Event

**Event ID:**
78415

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/06/2017

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

**Center Classification Date:**
11/22/2017

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

**Recalling Firm:**
West-Ward Pharmaceuticals Corp.
401 Industrial Way West
Eatontown NJ United States

**Distribution Pattern:**
Nationwide in the USA and Puerto Rico

## Associated Products

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|---|---|
| **Product Description:**<br>Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 1 mL Vials (NDC 0641-6145-01), packaged in 25 x 1 mL Vials per shelf pack (NDC 0641-6145-25), Rx Only, Manufactured by WEST-WARD, Eatontown, NJ 07724 USA. | **Product Quantity:**<br>16,157 shelf packs |
| **Reason for Recall:**<br>Failed Impurities/Degradation Specifications: high out of specification results for Dexamethasone adduct (related compound). | **Recall Number:**<br>D-0093-2018 |
| **Code Information:**<br>Lot #: 106390, 106393, 106395, Exp 10/18 | |

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|---|---|
| **Product Description:**<br>Dexamethasone Sodium Phosphate Injection, USP, 20 mg/5 mL (4 mg/mL), 5 mL Vials (NDC 0641-6146-01), packaged in 25 x 5 mL Vials per shelf pack (NDC 0641-6146-25), Rx Only, Manufactured by WEST-WARD, Eatontown, NJ 07724 USA. | **Product Quantity:**<br>1,896 shelf packs |
| **Reason for Recall:**<br>Failed Impurities/Degradation Specifications: high out of specification results for Dexamethasone adduct (related compound). | **Recall Number:**<br>D-0094-2018 |
| **Code Information:**<br>Lot #: 106352, Exp 10/18 | |