Enforcement Report - Week of June 3, 2020

Class II Drugs Event

Event ID:
85555

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/13/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/26/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Doxycycline Hyclate Tablets USP, 100 mg, packaged in a) 50-count bottle (NDC 0143-2112-50), b) 500-count bottle (NDC 0143-2112-05), Rx only, Mfd. by: West-Ward Pharmaceuticals Corp., Eatontown, NJ 07724.

Product Quantity:
68,376 bottles

Reason for Recall:
Failed dissolution specification: The dissolution test at the 24 month time point (end of shelf life) yielded an out of specification result.

Recall Number:
D-1274-2020

Code Information:
Lot #: a) 71846B, Exp 6/2021; b) 71726A, Exp 6/2020; 71846B, 71853A, Exp 6/2021

Class II Drugs Event

Event ID:
85724

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/15/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/26/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Doxycycline Hyclate tablets USP, 100 mg, packaged in bottles a) 6-count (NDC 55289-866-06), b) 10-count (NDC 55289-866-10), c) 14-count (NDC 55289-866-14), d) 20-count (NDC 55289-866-20), e) 28-count (NDC 55289-866-28), f) 30-count (NDC 55289-866-30), g) 60-count (NDC 55289-866-60), h) 120-count (NDC 55289-866-98), i) 210-count (NDC 55289-866-71), j) 300-count (NDC 55289-866-87), k) 400-count (NDC 55289-866-74), Rx only, PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127

Product Quantity:
14,030 bottles

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-1276-2020

Code Information:
Lots: a) L18B72, Exp 12/31/2020; b)I18B83, Exp 06/30/2020 ; c) H18B11, Exp 06/30/2020; I18A53, Exp 06/30/2020; J18F97, Exp 10/31/2020; K18A33, Exp 11/30/2020; K18D17, Exp 11/30/2020; L18A11, Exp 12/31/2020; L18A29, Exp 12/31/2020; L18D81, Exp 12/31/2020; d) H18F60, Exp 06/30/2020; I18C26, Exp 06/30/2020; I18D61, Exp. 06/30/2020; J18B80, Exp 10/31/2020; K18C97 Exp 11/30/2020; L18B30, Exp. 12/31/2020; L18D25, Exp 12/31/2020; L18E50 Exp 12/31/2020; e) I18D07, Exp. 06/30/2020; J1E02, Exp 10/31/2020; J18E62 Exp 10/31/2020; K18E98 Exp. 11/30/2020; L18C54, Exp 12/31/2020; f) H18E18 Exp. 06/30/2020, I18F94 Exp. 09/30/2020, J18E42, Exp. 10/31/2020, L18B56 Exp. 12/31/2020; g) J18C84 Exp. 10/31/2020, A19B70 Exp. 01/31/2021; h) K18E92 Exp. 11/30/2020; i) I18E80 Exp. 06/30/2020, K18A19 Exp. 11/30/2020; j) F18E11 Exp. 06/30/2020, G18E66 Exp. 06/30/2020, H18E72 Exp. 06/30/2020, I18E75 Exp. 09/30/2020, I18E95 Exp. 09/30/2020, I18F64 Exp. 09/30/2020; k) A19D44 Exp. 08/31/2020, H18E76 Exp. 06/30/2020, I18F21 Exp. 09/30/2020, L18B91 Exp. 12/31/2020

Class II Drugs Event

Event ID:
85726

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/28/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Wuhan Bingbing Pharmaceutical Co., Ltd.
Building F, No.5, Kangda Street
Wuhan China

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
LidoPatch (lidocaine HCl 3.6%, menthol 1.25%) Pain Relief Patch, packaged in 1 patch/box (NDC 10882-527-01); 30 patches/box (NDC 10882-527-02 and 10882-527-04), Manufactured for: JAR Laboratories, Elmhurst, IL.

Product Quantity:
4,960 boxes

Reason for Recall:
CGMP Deviations: due to the loss of product manufacturing records and retain product samples, there is no assurance that the product will remain within specification through the labeled expiration date.

Recall Number:
D-1277-2020

Code Information:
Batch #: 1180103, Exp 2021.01.02; 180104, Exp 2021.01.03; 80105, Exp 2021.01.04; 180106, Exp 2021.01.05; 80107, Exp 2021.01.06.

Product Description:
LidoPro (lidocaine 4%, menthol 5%, methyl salicylate 4%) patch, 15 Patches per box, Manufactured For: Terrain Pharmaceuticals, Reno, NV 89501; NDC 53225-1023-1.

Product Quantity:
54,000 boxes

Reason for Recall:
CGMP Deviations: due to the loss of product manufacturing records and retain product samples, there is no assurance that the product will remain within specification through the labeled expiration date.

Recall Number:
D-1278-2020

Code Information:
Batch #: 170527, Exp 2020.05

Product Description:
Mencaine (lidocaine 4.5%, menthol 5%) Patch, 1 patch per pouch, Manufactured For: Terrain Pharmaceuticals, Reno, NV 89501; NDC 53225-1090-1.

Product Quantity:
1,800 pouches

Reason for Recall:
CGMP Deviations: due to the loss of product manufacturing records and retain product samples, there is no assurance that the product will remain within specification through the labeled expiration date.

Recall Number:
D-1279-2020

Code Information:
Batch #: 170731, Exp 2020.07; 180504; Exp 2021.05

Product Description:
Maximum Strength Lidocaine Cold & Hot Patch (lidocaine 4%, menthol 1%), 5 patches per box, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895; NDC 66902-218-05.

Product Quantity:
72,600 boxes

Reason for Recall:
CGMP Deviations: due to the loss of product manufacturing records and retain product samples, there is no assurance that the product will remain within specification through the labeled expiration date.

Recall Number:
D-1280-2020

Code Information:
Batch #: 170614, Exp 2020.06.13; 180108, Exp 2021.01.07; 180109, Exp 2021.01.08; 180110, Exp 2021.01.09; 180111, Exp 2021.01.10, 180112, Exp 2021.01.11; 180113, Exp 2021.01.12; 180317, Exp 2021.03.16; 180318, Exp 2021.03.17

Class III Drugs Event

Event ID:
85752

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/26/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
TN

Associated Products

Product Description:
Lamotrigine Tablets, USP, 150 mg, 20,000-count bulk container, Manufactured by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801, USA, For repackaging by: AvKare Inc., Pulaski, TN 38478, Bulk Shipment, NDC 59746-247-97.

Product Quantity:
1,313,333 tablets

Reason for Recall:
Presence of Foreign Substance visually consistent with the silica granules present in the desiccant packs utilized during storage of the product.

Recall Number:
D-1281-2020

Code Information:
Lot #s 19P0437 & 19P0438, Exp. 09/30/2021.