Enforcement Report - Week of June 19, 2019

Class II Drugs Event

Event ID:
82941

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/23/2019

Voluntary / Mandated:
FDA Mandated

Center Classification Date:
06/07/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pharm D Solutions, LLC
1304 S Loop W
Houston TX United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Bacteriostatic Water for Injection, 10 mL vials, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
716 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1322-2019

Code Information:
Lot #: 11292018:75 Exp. 05/28/2019; 01022019:70 Exp. 07/01/2019; 02042019:04 Exp. 08/03/2019; 03042019:94 Exp. 08/31/2019

Product Description:
B-complex (Thiamine 100mg, Riboflavin 2mg, Niacinamide 100 mg, Pyridoxine 2mg, Depanthenol 5mg) injectable, 10 mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846, NDC 69699-1611-30

Product Quantity:
4 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1323-2019

Code Information:
Lot #: 04032019:23 Exp. 06/11/2019

Product Description:
Human Chorionic Gonadotropin 10,000 IU vials, Rx only Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
26 vails

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1324-2019

Code Information:
Lot #: 02052019:42 Exp. 08/03/2019

Product Description:
Human Chorionic Gonadotropin 5,000 IU vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
279 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1325-2019

Code Information:
Lot #: 01082019:88 Exp. 07/06/2019; 03182019:58 Exp. 09/14/2019

Product Description:
Human Chorionic Gonadotropin 12,000 IU vials Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
104 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1326-2019

Code Information:
Lot #: 01232019:86 Exp. 07/22/2019; 04042019:86 Exp. 10/01/2019

Product Description:
Ipamorelin Acetate 9 mg/9mL Injectable vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
11 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1327-2019

Code Information:
Lot #: 05022019:50 Exp. 10/29/2019; 05082019:91 Exp. 06/08/2019

Product Description:
Lipo MIC-12 (Methylcobalamin, USP 1mg, Methionine USP 15mg, Inositol, FCC 50mg, Choline Chloride, FCC 100 mg) 10 mL Injectable vials, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
669 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1328-2019

Code Information:
Lot #: 02202019:53/A Exp. 08/18/2019; 04012019:67/A, 04022019:47/A Exp. 09/28/2019; 04042019:04/A Exp. 09/30/2019; 04082019:38/A Exp. 10/02/2019; 04302019:49/A Exp. 10/27/2019; 05062019:09 Exp. 11/02/2019

Product Description:
Nandrolone Decanoate 200 mg/mL Injectable, 10 mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
50 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1329-2019

Code Information:
Lot #: 01312019:34 Exp. 07/30/2019

Product Description:
Sermorelin/Ipamorelin 18 mg/15 mg, 10mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
24 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1330-2019

Code Information:
Lot #: 04162019:48 Exp. 10/13/2019; 04302019:70 Exp. 10/27/2019; 05022019:34 Exp. 10/29/2019

Product Description:
Sermorelin/GHRP-2 9 mg/9 mg vials Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
6 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1331-2019

Code Information:
Lot #: 05082019:92 Exp. 06/04/2019

Product Description:
Sermorelin/GHRP-2 9 mg/6 mg vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
66 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1332-2019

Code Information:
Lot #: 03052019:43 Exp. 08/31/2019; 04042019:15 Exp. 10/01/2019; 04172019:08 Exp. 08/31/2019; 05022019:47 Exp. 10/30/2019; 05082019:78 Exp. 06/04/2019

Product Description:
Sermorelin/GHRP-2 & 6 (3-3-3 MG) vials, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
100 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1333-2019

Code Information:
Lot #: 12062018:17 Exp. 06/04/2019

Product Description:
Sermorelin/GHRP-2 &6 (9-9-9-mg) vials, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
1 vial

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1334-2019

Code Information:
Lot #: 05032019:29 Exp. 11/02/2019

Product Description:
Sermorelin/GHRP-2 &6 (9-9-9 mg) vials, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
25 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1335-2019

Code Information:
Lot #: 02182019:79 Exp. 08/17/2019; 04162019:86 Exp. 10/13/2019

Product Description:
Testosterone 200 mg/mL, 30 mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846, NDC 69699-1702-30

Product Quantity:
704 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1336-2019

Code Information:
Lot #: 10242018:70/B Exp. 08/31/2019; 10302018:63/A Exp. 08/31/2019

Product Description:
Testosterone Cyp/Pro 95/5%, 10 mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
371 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1337-2019

Code Information:
Lot #: 01312019:02 Exp. 08/16/2019; 02072019:45/A Exp. 11/30/2019

Product Description:
Testosterone Cypionate 200 mg/mL, in a) 5mL vials and b)10 mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846, NDC 69699-1702-10

Product Quantity:
a) 114 vials and b) 566 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1338-2019

Code Information:
Lot #: a) 10242018:70/P, Exp. 08/31/2019; b) 10242018:70/A Exp. 08/31/2019; 02262019:49/A Exp. 11/30/2019

Product Description:
Trimix 30mg/1 mg/10mcg/mL (30 mg Papaverine, 1mg phentolamine mesylate, 30 mcg alprostadil) Injectable, 5mL vials, Rx only, Pharm D. Solutions 1304 South Loop West, Houston, TX 77054, 1-844-263-6846

Product Quantity:
4 vials

Reason for Recall:
Lack of Sterility Assurance.

Recall Number:
D-1339-2019

Code Information:
Lot #: 05022019:90 Exp. 07/13/2019

Class II Drugs Event

Event ID:
82993

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/31/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/13/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Chiesi USA, Inc.
175 Regency Woods Place, Ste. 600
Cary NC United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
ZYFLO CR (zileuton) extended-release tablets, 600 mg, 120-count bottles, Rx only, Distributed by Chiesi USA, Inc., Cary, NC 27518, NDC 10122-902-12.

Product Quantity:
2118 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification result for dissolution.

Recall Number:
D-1341-2019

Code Information:
Lots: 3171855, Exp. 12/19

Product Description:
Zileuton Extended-Release Tablets, 600 mg, 120-count bottles, Rx only, Distributed by: Prasco Laboratories, Mason, OH 45040 USA; NDC 66993-485-32.

Product Quantity:
2598 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification result for dissolution.

Recall Number:
D-1342-2019

Code Information:
Lots: 3171856, Exp. 12/19

Class II Drugs Event

Event ID:
83019

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Estradiol Vaginal Inserts USP 10 mcg, packaged in box of 8 Vaginal Inserts (with disposable applicators), Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bardez, Goa 403 513 India, Manufactured for: Glenmark Pharmaceuticals Inc., Mahwah, NJ 07430 USA, NDC 68462-711-71

Product Quantity:
31,656 boxes

Reason for Recall:
Defective Delivery System: Estradiol Vaginal Inserts USP plunger is not functioning properly.

Recall Number:
D-1340-2019

Code Information:
Lot#: 20180516, Exp 4/30/2020

Not Yet Classified Drugs Event

Event ID:
82968

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/28/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novis PR, Inc.
320 Ave Barbosa
San Juan PR United States

Distribution Pattern:
Puerto Rico

Associated Products

Product Description:
Pecgen DMX Cough Suppressant Expectorant, Contains the same active ingredients as Trispec DMX, Sugar Free, Alcohol Free, Dye Free, Gluten Free, Cherry Raspberry Flavor, 16 Fl. oz. (474 mL), Manufactured in the USA for Kramer Novis, San Juan, PR 00917, www.kramernovis.com, NDC 52083-630-16.

Product Quantity:
5766 bottles

Reason for Recall:
Labeling: Incorrect Instructions; The product has been found to provide incorrect dosage information on its label due to a typographical error. The drug facts label incorrectly states children 6 to under 2 years of age, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or directed by physician. The label should state children 6 to under 12, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by physician. Additionally, the label does not advise consumers to consult a doctor for children under 2 years of age.

Recall Number:

Code Information:
Lot #s: D80202, D80210 Exp. 02/20; D80818, D80819 Exp. 09/20; D80820 Exp. 09/20