

IN THIS SECTION



COMPANY ANNOUNCEMENT

Pharm D Solutions, LLC Issues Voluntary Nationwide Recall of All Sterile Compounded Drugs Due to a Potential Lack of Sterility Assurance

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

May 23, 2019

FDA Publish Date:

May 24, 2019

Reason for Announcement:**Company Name:**

Pharm D Solutions, LLC

Brand Name:

Pharm D Solutions

Product Description:

Sterile Compounded Drug Products

Company Announcement

FOR IMMEDIATE RELEASE – Houston, Texas, Pharm D Solutions, LLC is voluntarily recalling all sterile compounded drug products within expiry to the consumer level. These drug products are being voluntarily recalled due to concerns that practices at the pharmacy have the potential to pose a risk of contamination to products that are intended to be sterile. These concerns arose following a routine inspection of the pharmacy by FDA.

Administration of a non-sterile product that is intended to be sterile by subcutaneous, intramuscular, intravenous or ocular routes of administration may result in serious injury or death. To date, Pharm D Solutions, LLC is not aware of any adverse events related to this recall. This voluntary recall is being conducted out of an abundance of caution and to promote patient safety, which is the pharmacy's highest priority.

The recall encompasses all compounded sterile drug products, within expiry, that were dispensed within from October 24, 2018 to May 21, 2019. The sterile drug products subject to this recall were distributed nationwide and directly to customers and/or medical facilities. The recall does not affect the pharmacy's non-sterile compounded products or retail pharmacy operations.

The pharmacy has notified potentially affected customers of the voluntary recall via U.S. Mail and direct outreach. Customers who have received sterile compounded products subject to the voluntary recall should stop using and return the product to the pharmacy for a full refund.

Consumers with questions regarding this recall can contact Pharm D Solutions, LLC by calling Luis R DeLeon or Carlos DeLeon at 1-844-263-6846, Monday through Friday between 10:00 a.m. and 4:30 p.m., CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: <http://www.fda.gov/medwatch/report.htm> (<http://www.fda.gov/medwatch/report.htm>)
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm (<http://www.fda.gov/MedWatch/getforms.htm>) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

| PRODUCT | LOT NUMBER |
|--|---------------|
| TESTOSTERONE CYPIONATE GS 200 MG/ML 10 ML | 10242018:70/A |
| TESTOSTERONE 200 MG/ML GRAPESEED OIL 30 ML 200 MG/ML | 10242018:70/B |
| HUMAN CHORIONIC GONADOTROPIN 3000 IU LYOPHILIZED | 10292018:21 |
| TESTOSTERONE 200 MG/ML GRAPESEED OIL 30 ML 200 MG/ML | 10302018:63/A |
| TESTOSTERONE CYPIONATE GS 200 MG/ML 5 ML | 10242018:70/P |
| BACTERIOSTATIC WATER FOR INJECTION 10 ML | 11292018:75 |
| SERMORELIN/GHRP-2/GHRP-6 3 MG/3 MG/3 MG LYOPHILIZED | 12062018:17 |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 12262018:69 |
| BACTERIOSTATIC WATER FOR INJECTION 10 ML 10 ML | 01022019:70 |

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| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 01072019:12 |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 01072019:88 |
| HUMAN CHORIONIC GONADOTROPIN 5000 IU LYOPHILIZED | 01082019:88 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 01172019:69 |
| HUMAN CHORIONIC GONADOTROPIN 12000 IU LYOPHILIZED | 01232019:86 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 01252019:94 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 01282019:55 |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 01292019:69 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 01312019:86 |
| TESTOSTERONE CYP/PRO 200 MG/10 MG /ML 10 ML INJECTABLE | 01312019:02 |
| NANDROLONE GS 10 ML 200 MG/ML INJECTABLE | 01312019:34 |
| BACTERIOSTATIC WATER FOR INJECTION 10 ML 10 ML INJECTABLE | 02042019:04 |
| HUMAN CHOIONIC GONADOTROPIN 10,000 IU LYOPHILIZED | 02052019:42 |
| TESTOSTERONE CYP/PRO 200 MG/10 MG /ML 10 ML INJECTABLE | 02072019:45/A |
| SERMORELIN/GHRP-2/GHRP-6 9 MG/9 MG/9 MG LYOPHILIZED | 02182019:79 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 02202019:53/A |
| TESTOSTERONE CYPIONATE GS 200 MG/ML 10 ML INJECTABLE | 02262019:49/A |
| BACTERIOSTATIC WATER FOR INJECTION 10 ML 10 ML INJECTABLE | 03042019:94 |
| SERMORELIN/GHRP-2 9 MG-6 MG LYOPHILIZED | 03052019:43 |
| HUMAN CHORIONIC GONADOTROPIN 5000 IU LYOPHILIZED | 03182019:58 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 04012019:67/A |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 04022019:47/A |
| B-COMPLEX B-1,B-6,B-3,B-12,B-5 100,2.54 INJECTABLE 10 ml | 04032019:23 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 04042019:04/A |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 04042019:61 |
| SERMORELIN/GHRP-2 9 MG-6 MG LYOPHILIZED | 04042019:15 |
| HUMAN CHORIONIC GONADOTROPIN 12000 IU LYOPHILIZED | 04042019:86 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 04082019:38/A |
| SERMORELIN/GHRP-2/GHRP-6 9 MG/9 MG/9 MG LYOPHILIZED | 04162019:86 |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 04162019:48 |
| SERMORELIN/GHRP-2 9 MG-6 MG LYOPHILIZED | 04172019:08 |
| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 04302019:49/A |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 04302019:70 |
| IPAMORELIN ACETATE 9 MG INJECTABLE | 05022019:50 |
| TRIMIX PAPAVERINE/PHENTOLAMINE/ALPROSTADIL 30 MG / 1 MG /10 MCG/ML INJECTABLE | 05022019:90 |
| SERMORELIN / IPAMORELIN 18 MG/ 15 MG LYOPHILIZED | 05022019:34 |
| SERMORELIN/GHRP-2 9 MG-6 MG LYOPHILIZED | 05022019:47 |
| SERMORELIN/GHRP-2/GHRP-6 9 MG/9 MG/9 MG LIQUID | 05032019:29 |

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| LIPO MIC-12 METHIONINE/INOSITOL/CHOLINE/METHYLCOBALAMIN 10 ML 15 MG/50 MG/100 MG/1 MG INJECTABLE | 05062019:09 |
| IPAMORELIN ACETATE 9 MG INJECTABLE | 05082019:91 |
| SERMORELIN/GHRP-2 9 MG/9 MG LYOPHILIZED | 05082019:92 |
| SERMORELIN/GHRP-2 9 MG-6 MG LYOPHILIZED | 05082019:78 |

Company Contact Information

Consumers:

Luis R De Leon

☎ 713-790-1693

Product Photos

BACTERIOSTATIC WATER FOR INJECTION 10 ML

For drug diluent use only. 0.8% benzyl alcohol added. Sterile nonpyrogenic. Use only if clear and seal is intact and undamaged. For dilution only. This is a compounded product. **HOT FOR USE IN RECHARGES**. Store at controlled room temperature.



Database Entry Reporting:
www.fda.gov/medwatch
1-866-FDA-1088

Pharm D Solutions 1166 South Loop
West Houston, TX 77058
1-866-763-6666

Date Made: 11/29/2018
Lot: 11292018:75
Exp: 5/29/2019

HUMAN CHORIONIC GONADOTROPIN 5000 IU

Each vial contains 5000 IU HCG, 10 mg of fructose dihydrate, 5 mg of ribitol, 15 mg of sodium phosphate dihydrate, 1 mg of sodium phosphate monobasic. Reconstitute with bacteriostatic water. Discard 30 days after reconstitution. Store at refrigerated temperature. This is a compounded drug.



Rx Use Only

Database Entry Reporting:
www.fda.gov/medwatch
1-866-FDA-1088

Pharm D Solutions 1166 South Loop
West Houston, TX 77058
1-866-763-6666

Date Made: 1/8/2019
Lot: 01082019:28
Exp: 7/8/2019

IPAMORELIN 9 MG/9 ML

Each 1 ml contains ipamorelin acetate 1 mg and 110 mg trehalose qs to 9 mL with bacterostatic water. Store at controlled room temperature. RX only. This is a compounded medication.

Adverse Event Reporting:
www.fda.gov/medwatch and
1- 800-FDA-1088

Pharm D. Solutions 1304 South Loop
West, Houston, TX 77054
1-844-263-6846

Date Made: 5/2/2019
Lot: 05022019:50
Exp: 10/29/2019

LIPO-MIC B12 10 ML

Each 1ml contains Methylcobalamin, USP 1 mg, Methionine USP 15mg, Inositol, FCC 50mg, Choline Chloride, FCC 100 mg in sterile water for injection. Preserved with 0.2% benzyl alcohol. Store refrigerated at 2°C to 8°C, discard 30 days after puncture. pH adjusted 7.0 (6.5 to 7.5) NaOH or HCL For Injection Only. This is a compounded drug.

Adverse Event Reporting:
www.fda.gov/medwatch and
1- 800-FDA-1088

Pharm D. Solutions 1304 South Loop
West, Houston, TX 77054
1-844-263-6846

Date Made: 4/8/2019
Lot: 04082019:38/A
BUD: 10/2/2019

SERMORELIN/GHRP-2 & 6 (3-3-3 MG)

For IM or SQ Injection. Each lyophilized vial contains 3mg Sermorelin Acetate, USP, 3mg Growth Hormone Releasing Peptide-2 (GHRP), 3mg GHRP-6 57mg Mannitol, USP, 110 MG Trehalose, USP Reconstitue with up to 10 ml bacteriostatic water for injection. Discard 30 days after puncture. Store at refrigerated temperature upon reconstitution. This is a compounded drug.

Adverse Event Reporting:
www.fda.gov/medwatch and
1- 800-FDA-1088

Pharm D. Solutions 1304 South Loop
West, Houston, TX 77054
1-844-263-6846

Date Made: 12/6/2018
Lot: 12062018:17
Exp: 6/4/2019

Rx Only **SERMORELIN-IPAMORELIN 18 MG / 15 MG**

For IM or SQ Injection. Each mL contains 1.8 mg Sermorelin Acetate, 1.5 mg Ipamorelin. Reconstituted with 10 mL bacteriostatic water. Store at refrigerated temp. This is a compounded drug. Total Volume: 10 mL.

Adverse Event Reporting:
www.fda.gov/medwatch and
1- 800-FDA-1088

Pharm D. Solutions 1304 South Loop
West, Houston, TX 77054
1-844-263-6846

Date Made: 5/2/2019
Lot: 05022019:34
Exp: 10/29/2019

For office use only/ Not for Re-sale/ RX only

NDC: 68555-1702-30

TESTOSTERONE CYPIONATE 200 MG/ML 30 ML

Each 1ml contains Testosterone Cypionate USP 200 mg, 0.2 ml Benzyl Benzoate, Benzyl Alcohol 0.02 mL in grape seed oil USP.
For IM Injection, Non-pyrogenic. Discard after 30 days once opened. Store at 20°C to 25°C (68° to 77°F). Protected from freezing. This is controlled substance. This is a compounded drug.

C-III

Adverse Event Reporting: Pharm D Solutions 1304 South Loop West, Houston, TX 77054 1-844-263-6846
 www.fda.gov/medwatch Lot: 10242018.7 Q/V
 Date Made: 10/25/2018 Exp: 8/31/2019

Not for Re-sale/ RX only

Item# 68555-1702-10

TESTOSTERONE CYP. 200 MG/ML 10 ML

Each 1ml contains Testosterone Cypionate USP 200mg, 0.2 ml Benzyl Benzoate, Benzyl Alcohol 0.02m L in grape seed oil USP;
For IM Injection, Non-pyrogenic. Discard after 30 days once opened. Store at 20°C to 25°C (68° to 77°F). Protected from freezing. This is a compounded drug.

C-III

Adverse Event Reporting:
 www.fda.gov/medwatch
 1-866-FDA-1088

Pharm D Solutions 1304 South Loop
 West, Houston, TX 77054
 1-844-263-6846

Date Made: 2/27/2019
 Lot: 02252019.4 B/A
 Exp: 1/30/2019

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