

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 08/30/2021-09/23/2021
	<small>FEI NUMBER</small> 3013207472

<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Jacqueline Anne Thibodeau - Pharmacy Development Director
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<small>FIRM NAME</small> Promise Pharmacy, LLC	<small>STREET ADDRESS</small> 31818 US Highway 19 North
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<small>CITY, STATE, ZIP CODE, COUNTRY</small> Palm Harbor, FL 34684-3713	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drug Products
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.


DURING AN INSPECTION OF YOUR FIRM, I OBSERVED:

OBSERVATION 1

You used a non-pharmaceutical grade component in the formulation of a drug product. Specifically, your firm routinely uses non-pharmaceutical grade components for compounding drug products. A review of the Certificate of Analysis for various components noted:

1) Non-pharmaceutical grade components were used in processing injectable drug products for example:

- (b) (4) Lot #(b) (4) & Lot (b) (4) were used in compounding TRIM Thermal Lot #02042021@5 BUD 03/21/2021.
- (b) (4) Lot #(b) (4) was used in compounding TRIM Thermal Lot #02042021@5 BUD 03/21/2021.
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- (b) (4) Lot (b) (4) was used in compounding TRIM Calm Lot #07282021@1 BUD 11/05/2021.
- (b) (4) (98%) Lot (b) (4) was used in compounding TRIM Calm Lot #07282021@1 BUD 11/05/2021.
- Ipamorelin Acetate Lot (b) (4) was used in compounding Ipamorelin/Sermorelin PF 15mg/15mg injectable Lot #08192021@4 BUD 03/17/2022.
- Sermorelin Acetate Lot #(b) (4) was used in compounding Ipamorelin/Sermorelin PF 15mg/15mg injectable Lot #08192021@4 BUD 03/17/2022.
- Thymosin B4 Acetate Lot (b) (4) was used in compounding Thymosin B4 PF 15mg injectable Lot #08192021@3 BUD 02/15/2022.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> 	<small>EMPLOYEE(S) NAME AND TITLE (Print or Type)</small> Marvin D. Jones - Investigator	<small>DATE ISSUED</small> 09/23/2021
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		<small>FBI NUMBER</small> 3013207472
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Jacqueline Anne Thibodeau - Pharmacy Development Director		
<small>FIRM NAME</small> Promise Pharmacy, LLC	<small>STREET ADDRESS</small> 31818 US Highway 19 North	
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- Epithalon Acetate Lot (b) (4) was used in compounding Epithalon PF 15mg injectable Lot #08192021@1 BUD 02/15/2022.
- Kisspeptin-10 Acetate Lot #(b) (4) was used in compounding Kisspeptin-10 1mg/ml (3ml) injectable Lot #08242021 @1 BUD 02/20/2022.
- Deoxycholic Acid Lot #(b) (4) was used in compounding Phosphatidycholine 5% 50mg/ml injectable Lot #08232021@2 BUD 01/20/2022.
- Glycyrrhizic Acid Lot (b) (4) was used in compounding Glycyrrhizic Acid PF 8mg/ml injectable Lot #08112021@2 BUD 09/25/2021.
- Melanotan II Acetate Lot (b) (4) was used in compounding Melanotan II PF 10mg injectable Lot #06242021@1 BUD 12/18/2021.
- BPC-157 Acetate Lot # (b) (4) was used in compounding BPC-157 PF 10mg Vial injectable Lot #08052021@2 BUD 02/01/2022.
- (b) (4) Lot (b) (4) was used in compounding TRIM Complete Lot #08242021@4 BUD 10/08/2021.

2) Non-pharmaceutical grade components were used in processing non-sterile drug products for example:

- Green Tea Powder Extract Lot #(b) (4) was used in compounding Revitalizing Eye Cream Lot #08312021@31 BUD 09/30/2021.
- Kisspeptin-10 Acetate Lot #(b) (4) was used in compounding Kisspeptin-10 200mcg Troche Lot #08192021@9 BUD 02/15/2022.
- BPC-157 Acetate Lot (b) (4) was used in compounding BPC 157 0.5mg Capsule Lot #07142021@10 BUD 01/10/2022.
- AOD9604 Acetate Lot (b) (4) was used in compounding AOD 0.5mg Troche Lot #06152021@28 BUD 12/12/2021.

OBSERVATION 2

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves. Specifically,

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> 	<small>EMPLOYEE(S) NAME AND TITLE (Print or Type)</small> Marvin D. Jones - Investigator	<small>DATE ISSUED</small> 09/23/2021
<small>FORM FDA 483 (09/08)</small>		<small>PREVIOUS EDITION OBSOLETE</small>	<small>INSPECTIONAL OBSERVATIONS</small>

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Jacqueline Anne Thibodeau - Pharmacy Development Director

FIRM NAME

Promise Pharmacy, LLC

STREET ADDRESS

31818 US Highway 19 North

CITY, STATE, ZIP CODE, COUNTRY

Palm Harbor, FL 34684-3713

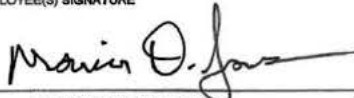
TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drug Products

On 08/30/2021, I observed a technician touch with their gloved hands a formulation worksheet located outside of the ISO 5 hood and then return to the inside of the ISO 5 hood to continue processing an injectable drug product without sterilizing their gloved hands. The technician was processing the injectable drug product LIPO-C Lot# 08302021@1 BUD 11/28/2021 contained in (b) (4) vials.

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EMPLOYEE(S) NAME AND TITLE (Print or Type)

Marvin D. Jones - Investigator

DATE ISSUED

09/23/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."