DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/15/2018-10/25/2018* FEI NUMBER 3013207472

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mipal (Amy) Patel, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Promise Pharmacy, LLC	31818 US Highway 19 N
CITY, STATE, ZIP CODE, COUNTRY Palm Harbor, FL 34684-3713	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile products

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not.

Specifically, on 10/19/18, I observed the following:

- An operator blocked first pass HEPA filtered air during the production of Bremelanotide, Lot 1019018@4, BUD 12/18/18.
- An operator did not move slow and deliberate in the ISO 5 environment when transferring partially stoppered vials of Bremelanotide, Lot 1019018@4, BUD 12/18/18, from the compounding table to (b) (4)
- An operator did not wear a beard cover during the production of HCG 2000IU Injectable, Lot 10192018@6, BUD 04/17/18.

OBSERVATION 2

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically, your firm does not perform a visual examination of finished drug products prior to dispensing and distribution. On 10/16/18, I observed the presence of particulates in multiple bottles of Prednisolone and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Huntington, Investigator	X Jennifer L Huntington Investigator Signed By: Jennifer L. Huntington Date Signed: 10-25-2018 06:01:04	10/25/2018

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Gatifloxacin Ophthalmic Solution, Lot 09042018@2, BUD 12/03/18.(b) (4) bottles of Prednisolone and Gatifloxacin Ophthalmic Solution, Lot 09042018@2 had already been dispensed and distributed.

OBSERVATION 3

The flow of components, drug product containers, closures and in-process materials though the building is not designed to prevent contamination.

Specifically,

A. The environment in which sterile, non-hazardous drug products are produced does not meet the standards of an ISO 5 environment due to the following:
   - HEPA filters do not cover the entire room.
   - There is no full assessment of the room's pressure differentials.
   - Smoke studies were not performed throughout the entire room.
   - There is a non-classified (b) (4) from the ISO 8 Prep room to the ISO 5 sterile environment.

B. On 10/18/18, I observed the transfer of partially stoppered Bremelanotide, Lot 10192018@4, from the stainless-steel compounding table to the (b) (4) in the ISO 5 sterile, non-hazardous room. I observed the (b) (4) is partially located under a light fixture that does not have a HEPA filter.

OBSERVATION 4

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

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Specifically, your firm does not perform sterility and endotoxin testing on batches of sterile hazardous and non-hazardous drug products of (b) (4) vials/bottles or less. Examples include, but are not limited to:

- Ascorbic Acid Injection 450mg/mL Injectable, Lot 07202018@19, BUD 09/03/18
- Arginine HCL 200mg/mL Injectable, Lot 02082018@13, BUD 03/25/18
- Magnesium Sulfate 500mg/mL Injectable, Lot 08282018@2, BUD 10/12/18

OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

A. Your firm does not perform potency testing on all batches of sterile drug products prior to release and distribution. Examples include, but are not limited to:
   - Ascorbic Acid 450mg/mL Injectable, Lot 07062018@2, BUD 08/20/18
   - Magnesium Sulfate 500mg/mL, Lot 08282018@2, BUD 10/12/18
   - Dexpanthenol USP 250mg/mL, Lot 02082018@15, BUD 03/25/18
   - Sermorelin GHRP 6 GHRP 2 PF 6mg/3mg/3mg Injectable, Lot 08302018@13, BUD 02/26/19

B. Your firm released and distributed (b) (4) vials of Bremelanotide (PT141) 20mg Injectable, Lot 05312018@4, BUD 07/30/18, with super-potent results for Bremelanotide of 114.3% (specifications (b) (4)

C. Your firm released and distributed (b) (4) vials of Sermorelin GHRP 6 GHRP 2 PF 6mg/3mg/3mg Injectable, Lot 05312018@3, BUD 11/27/18, with super-potent results for GHRP-2 of 112.4% (specifications (b) (4) and GHRP-6 of 113.8% GHRP-6 (specifications (b) (4) .

D. Your firm released and distributed (b) (4) vials of Sermorelin GHRP 6 GHRP 2 PF 9mg/9mg/9mg

Injectable, Lot 05242018@2, BUD 11/20/18, with super-potent results for GHRP-6 of 111.3% (specifications (b) (4)

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm lacks written procedures for a continuous stability program; and your firm does not perform stability testing for sterility or endotoxin on sterile hazardous and non-hazardous drug products. For example, Stability/BUD study for Ascorbic Acid 450mg/mL Injectable, Lot 05012018@42 to extend the BUD from 45 days to 90 days did not have sterility or endotoxin testing at the final test time point dated 07/27/18.

OBSERVATION 7

Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the validation of your firm's (b) (4) and (b) (4) lack temperature mapping to ensure the required internal temperatures are reached and maintained throughout batch for the required runtime.

OBSERVATION 8

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

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A. Quality Related Event Report (QRE) dated 06/26/18: A complaint was received for Rx# (b) (6) for particles floating in the injectable a few days after reconstitution for AOD 9604 PF 6mg Injection, Lot 06182018@3, BUD 09/16/18. Your firm performed an investigation confirming the presence of particles for multiple lots of AOD 9604 PF 6mg Injection. The probable root cause was identified as a problem with the AOD powder, Lot (b) (4) used to produce the batches. Your firm failed to perform a risk assessment assessing the impact and to take corrective actions, if indicated, regarding the following AOD injectable batches using AOD powder, Lot (b) (4) that were released and distributed: 01162018@14, 03192018@2, 05142018@4, and 06182018@3.QRE dated 02/09/18.

B. On 02/09/18, your firm identified a sterility failure for Thymosin B4 PF 15MG Injectable, Lot 01312018@1, BUD 05/01/18. Your firm failed to take appropriate corrective actions; to perform a risk assessment assessing the impact on other batches produced from (b) (4) (date reported); and to take corrective actions, if indicated, regarding the following batches produced in your firm's ISO 5 sterile, non-hazardous room from (b) (4)

- Sermorelin PF 15mg Injectable, Lot 01312018@2, BUD 07/30/18
- BPC-157 PF 10mg vial Injectable, Lot 01312018@3, BUD 01/31/18
- Arginine HCL, 200mg/mL Injectable, Lot 02082018@13, BUD 03/25/18
- Leucine/Isoleucine/Valine 10mg/10mg/5mg/mL PF Injectable, Lot 02082018@4, BUD 03/10/18
- Dexpanthenol USP 250mg/mL Injectable, Lot 02082018@15, BUD 03/25/18
- Ascorbic Acid Injection 500mg/mL Injectable, Lot 02082018@11, BUD 03/10/18
- Ascorbic Acid Injection 500mg/mL Injectable, Lot 02072018@1, BUD 03/09/18

***DATES OF INSPECTION**

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10/15/2018(Mon), 10/16/2018(Tue), 10/17/2018(Wed), 10/19/2018(Fri), 10/22/2018(Mon), 10/23/2018(Tue), 10/25/2018(Thu)

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