	T OF HEALTH AND HUMAN SERVICES DD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION		
555 Winderley Place, Suite 200	10/15/2018-10/25/2018*		
Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	FEI NUMBER 3013207472		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	ji j		
Mipal (Amy) Patel, Pharmacist-In-C	harge		
FIRM NAME	STREET ADDRESS		
Promise Pharmacy, LLC	31818 US Highway 19 N		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Palm Harbor, FL 34684-3713	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 Jennifer L Huntington,	Investigator	Jennifer L Huntington investigator Softed by Jennifer L Huntington X Date Stanet 10-25-2018 06 01 04	DATE ISSUED 10/25/2018
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DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	J AND DROG ADMINISTRATI	DATE(S) OF INSPECTION 10/15/2018-10/25/2018* FEI NUMBER 3013207472
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Mipal (Amy) Patel, Pharmacist-In-Ch FIRM NAME	street address	
Promise Pharmacy, LLC	31818 US	Highway 19 N
CITY, STATE, ZIP CODE, COUNTRY Palm Harbor, FL 34684-3713	type establishme Producer products	of sterile and non-sterile
Gatifloxacin Ophthalmic Solution, Lot 090420 OBSERVATION 3 The flow of components, drug product con building is not designed to prevent contami Specifically,	tainers, closures and	•
 A. The environment in which sterile, non-of an ISO 5 environment due to the foll HEPA filters do not cover the entir There is no full assessment of the r Smoke studies were not performed There is a non-classified ^{(b) (4)} 	lowing: re room. room's pressure differ throughout the entire	

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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Promise Pharmacy, LLC	31818 US Highway 19 N			
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Palm Harbor, FL 34684-3713 Producer of sterile and non-sterile products				
 Specifically, your firm does not perform sterility and e hazardous drug products of ⁽⁰⁾⁽⁴⁾ vials/bottles or less. Exar Ascorbic Acid Injection 450mg/mL Injectable, I Arginine HCL 200mg/mL Injectable, Lot 02082 Magnesium Sulfate 500mg/mL Injectable Lot 0 	Lot 07202018@19, BUD 09/03/18 2018@13, BUD 03/25/18			

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 ¹⁰¹⁽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

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INSPECTIONAL OBSERVATIONS

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NAME AND TITLE OF INDIVIDUAL TO W	HOM REPORT ISSUED			
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Palm Harbor, FL	34084-3713	Producer of ster products	Clie and non-su	eriie
 A. Quality Related Event Report (QRE) dated 06/26/18: A complaint was received for Rx# ^[b](^b) (^b) 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 ^[D](^d) 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 ^[D](^d) 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 ^[D](^d) (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 ^[D](^d) Semorelin PF 15mg Injectable, Lot 01312018@2, BUD 01/31/18 BPC-157 PF 10mg vial Injectable, Lot 01312018@3, BUD 03/25/18 Leucine/Isoleucine/Valine 10mg/10mg/5mg/mL PF Injectable, Lot 00202018@4, BUD 03/10/18 Dexpanthenol USP 250mg/mL Injectable, Lot 02082018@13, BUD 03/25/18 Ascorbic Acid Injection 500mg/mL Injectable, Lot 02072018@1, BUD 03/09/18 *DATES OF INSPECTION				
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