

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Food and Drug Administration 22215 26th Ave. SE, Suite 210 Bothell, WA 98021 Phone: 425-302-0340 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/21/2019-11/27/2019*
	FEI NUMBER 3003429652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Tyler M. Treharne, Pharm.D., Owner/Founder

FIRM NAME New Era Pharmacy, LLC	STREET ADDRESS 1286 SE Holgate Blvd., C-2
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CITY, STATE AND ZIP CODE Portland, OR 97202	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile drugs
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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) (WE) OBSERVED:

OBSERVATION 1

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, on 11/22/19, an employee was observed wearing a non-sterile face mask and a non-sterile knee-length gown. The non-sterile sleeves of his gown were inside the ISO 5 Biological Safety Cabinet during sterile production of HCG Microdose 1000 IU/10 mL (50 IU/ 0.5 mL) Injectable, Lot HM-1122S19, expiration date 12/6/19.

OBSERVATION 2

ISO-5 classified areas were not certified under dynamic conditions.

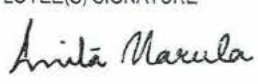
Specifically, the dynamic smoke studies conducted on 10/16/19 and 4/3/19 in the ISO 5 Bio-Safety Cabinet used to produce hazardous drugs and ISO 5 Laminar Flow Hood used to produce non-hazardous drugs are inadequate in that there are no videos or adequate written description available to verify the operator movement, interventions, equipment, etc.

OBSERVATION 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, media fills are not performed in a manner that simulates challenging production practices such as maximum number of people in the room, the duration of aseptic production and representative container type and

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size used during routine aseptic operations. For example:

A) The media fill for high risk production includes filling of (b) (4) vial which does not represent all vial sizes such as (b) (4) in a 10 ml vial and (b) (4) in a 2mL vial and (b) (4) in a 10 mL plastic dropper container used for ophthalmic products.

B) The media fill for low/medium risk production includes filling of (b) (4) which does not represent all vial sizes such as 10 mL in (b) (4) vial and (b) (4) in a 2mL vial.

OBSERVATION 4

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, your firm has been using non-pharmaceutical grade (b) (4) (b) (4) in the production of non-sterile drug products. For example:

A) Your firm used non-pharmaceutical grade (b) (4) to prepare (b) (4) (b) (4) and other solutions such as (b) (4) solution that were used in the production of non-sterile drug products. Some examples include:

- 1) Omeprazole (SP) 4 mg/ mL Suspension, Lot O111219@5 that was made on 11/12/19 used (b) (4) (b) (4) solution prepared using (b) (4), Lot (b) (4).
- 2) Oxytocin Nasal Spray 125 units/ mL Liquid, Lot O081319@4 that was made on 8/13/19 used (b) (4) (b) (4) Liquid prepared using (b) (4); Lot (b) (4).
- 3) Buprenorphine (VET) 0.3 mg/ mL Solution, Lot 11252019@5 that was made on 11/25/19 used (b) (4) (b) (4) Liquid prepared using (b) (4), Lot (b) (4).
- 4) Omeprazole (SP) 5 mg/ mL Suspension, Lot 11062019@4 that was made on 11/6/19 used (b) (4) (b) (4) solution prepared using (b) (4), Lot (b) (4).

B) In addition, your firm does not perform analytical or microbiological testing of this non-pharmaceutical grade (b) (4) to show if (b) (4) meets the specifications for (b) (4).

Add Continuation Page

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DATES OF INSPECTION:
 11/21/2019 (Thu), 11/22/2019 (Fri), 11/25/2019 (Mon), 11/26/2019 (Tue) and 11/27/2019 (Wed).

AW 11/27/19

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