DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE(S) OF INSPECTION
11/21/2019-11/27/2019*

Firm Name: New Era Pharmacy, LLC
Street Address: 1286 SE Holgate Blvd., C-2
City, State and Zip Code: Portland, OR 97202
Type of Establishment Inspected: Producer of Sterile and Non-sterile drugs

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

A) Your firm used non-pharmaceutical grade \((b) (4)\) to prepare \((b) (4)\) 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 \((b) (4)\) 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 \((b) (4)\) 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 \((b) (4)\) 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 \((b) (4)\) 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 \((b) (4)\).
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

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<tr>
<th>DISTRICT OFFICE ADDRESS AND PHONE NUMBER</th>
<th>DATE(S) OF INSPECTION</th>
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<tbody>
<tr>
<td>Food and Drug Administration</td>
<td>11/21/2019-11/27/2019*</td>
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<tr>
<td>22215 26th Ave, SE, Suite 210</td>
<td></td>
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<tr>
<td>Bothell, WA 98021</td>
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<tr>
<td>Phone: 425-302-0340</td>
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<td>Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a></td>
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**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

**CITY, STATE AND ZIP CODE**  
Portland, OR 97202

**TYPE OF ESTABLISHMENT INSPECTED**  
Producer of Sterile and Non-sterile drugs

**DATES OF INSPECTION:**  

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**EMPLOYEE(S) SIGNATURE**  
Anita Narula, Ph.D., CSO (Biotechnology)

**DATE ISSUED**  
11/27/2019

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