U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

February 18, 2020

Laura Carrillo
Executive Administrator
Alaska State Board of Pharmacy
P.O. Box 110806
Juneau, AK 99811-0806
Laura.Carrillo@alaska.gov

Dear Ms. Carrillo:

The purpose of this letter is to refer to the Alaska State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Alaska BOP, Geneva Woods Pharmacy, dba Geneva Woods Professional Infusion Pharmacy, located at 501 W. International Airport Road, Suite 4, Anchorage, AK 99518-1106 (Pharmacy License #142465).

FDA inspected the firm from November 26, 2018 to December 7, 2018. The Alaska State BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/123404/download, with any non-public information redacted.

Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain non-public information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Geneva Woods Infusion Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

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During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated and personnel were observed with exposed hands and hair during aseptic operations.

2. The design of the facility included the use of a transfer vestibule allowing the potential influx of non-classified air into the ISO 7 classified compounding room.

3. Disinfecting agents used in the ISO 5 classified aseptic processing areas were not sterile.

4. Adequate product evaluation and remedial action was not performed when actionable microbial contamination was found in areas adjacent to ISO 5 classified aseptic processing areas.

5. Disinfectant contact time (“dwell time”) and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

6. Adequate smoke studies were not performed under dynamic conditions to demonstrate unidirectional airflow of the ISO 5 classified aseptic production area.

7. Media fills were not performed under the most challenging or stressful conditions.

Geneva Woods Pharmacy, dba Geneva Woods Infusion Pharmacy committed to correct the deviations in its written responses to FDA dated December 28, 2018, January 30, 2019, March 22, 2019, and August 12, 2019, and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Alaska State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact CAPT Matthew Dionne, Compliance Officer, at 303-236-3064, or by email at Matthew.Dionne@fda.hhs.gov.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mrd

Cc: Cara Hagemeyer, Senior Branch Manager
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