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

February 6, 2020

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

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 practices observed during an FDA inspection at a pharmacy licensed by the Alaska BOP, Geneva Woods Pharmacy, Inc. dba Geneva Woods Pharmacy, located at 501 W. International Airport Road, Suite 20, Anchorage, AK 99518-1106 (Pharmacy License# PHAR398).

FDA inspected the firm from April 9, 2019, to April 16, 2019. Alaska 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/124961/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 Code of Federal Regulations (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 nonpublic 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 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.

Additionally, during the inspection, the FDA investigator observed deviations from appropriate 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:

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1. Beta-lactam drugs were produced without providing adequate containment, cleaning of work surfaces, utensils/equipment and personnel to prevent cross-contamination.

2. Hazardous drugs were produced without providing adequate cleaning of utensils/equipment to prevent cross-contamination.

Geneva Woods Pharmacy committed to FDA in its responses to the Form FDA 483 received April 30, 2019, and July 9, 2019, to correct the deviations in the Form FDA 483. In addition, the deviations identified appeared to be readily correctable. Furthermore, in their most recent response, dated November 12, 2019, the firm stated that the site is no longer used as a compounding facility as of June 2019.

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 R. 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