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

VIA EMAIL CONFIRMED DELIVERY
RETURN RECEIPT REQUESTED

June 30, 2023

Joseph Schnabel
Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
Joseph.Schnabel@oregon.gov

Ref: CMS 642688, FEI 3014745182

Dear Dr. Schnabel:

The purpose of this letter is to refer to you, the Oregon Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's concerns about poor practices observed during an FDA inspection at a pharmacy you licensed, Hiers Enterprises LLC dba Northwest Compounding Pharmacy, located at 1350 NE Stephens Street, Suite #42, Roseburg, OR 97470.

The FDA inspected the firm from November 2, 2021, to November 10, 2021. You were 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/156961/download, with any nonpublic information redacted. Additionally, an Untitled Letter dated September 22, 2022, was issued to the firm and can be found at https://www.fda.gov/media/163090/download. 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 the FDA will provide to the firm, which contains additional information about our inspection. 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 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for drug products compounded by Hiers Enterprises LLC dba Northwest Compounding Pharmacy, and the FDA does not intend to take further actions at this time related to

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conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Additionally, 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 but are not limited to:

1. The firm produced hazardous drugs without providing adequate containment and cleaning of utensils to prevent cross-contamination.
2. The firm produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, and cleaning of utensils to prevent cross-contamination.

Hiers Enterprises LLC dba Northwest Compounding Pharmacy committed to the FDA in its response to the Form FDA 483 received December 7, 2021, and in its response to the Untitled Letter received November 30, 2022, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the records, the FDA does not intend to take further action at this time with regard to the findings of this inspection. The FDA believes that the corrective actions can be appropriately overseen by the state. Therefore, the FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the state, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products 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 LCDR Rumany Penn, compliance officer, at 949-608-4409, or by email at Rumany.Penn@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Lance De Souza

Lance M. De Souza
Acting Director, Division of Pharmaceutical Quality Operations IV

LD:rp

cc: George M. Hiers IV
Owner and Pharmacist-in-Charge
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