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

VIA EMAIL CONFIRMED DELIVERY
RETURN RECEIPT REQUESTED

September 22, 2022

George M. Hiers IV
Owner and Pharmacist-in-Charge
Hiers Enterprises LLC dba Northwest Compounding Pharmacy
1350 NE Stephens Street, Suite #42
Roseburg, OR 97470-6410
nwcompounding@yahoo.com

Dear Dr. Hiers:

From November 2, 2021, to November 10, 2021, a U.S. Food and Drug Administration investigator inspected your facility, Hiers Enterprises LLC dba Northwest Compounding Pharmacy, located at 1350 NE Stephens Street, Suite #42, Roseburg, OR 97470. During the inspection, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

The FDA issued a Form FDA 483 to your firm on November 10, 2021. The FDA acknowledges receipt of your facility's response, dated December 7, 2021. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a state licensed pharmacy or a federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or

rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

1. You produced hazardous drugs without providing adequate containment and cleaning of utensils to prevent cross-contamination.
2. You produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, and cleaning of utensils to prevent cross-contamination.
3. Personnel did not change gloves frequently enough to prevent contamination.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding your responses related to the insanitary conditions, some of your corrective actions appear adequate; however, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. We acknowledge your response, "We are currently developing and instituting a plan to conform with USP 800. This will provide the containment desired. We are also finding and will begin using appropriate disposable wipes for cleaning utensils between materials." However, you did not provide details for instituting your plan, including, but not limited to, timelines for completion or construction or purchasing plans for USP<800> conformance. You also did not provide details about which disposable wipes you will use, your process, or if they will be sufficient to prevent cross contamination. You also did not provide evaluation of product currently in the market and did not provide current mitigation strategies while you are still producing hazardous drugs before you implement your USP <800> compliant room.
2. We acknowledge your response to conform to USP <800> and that you have developed procedures for cleaning. However, you did not provide your procedures. Also, you did not provide evaluation of product currently in the market and did not provide current mitigation strategies while you are still producing beta lactam drugs before you are able to implement your USP <800> compliant room.
3. We acknowledge your statement that you have developed and implemented training and procedures to address frequency for glove changes. However, you did not provide the procedure or details in your response.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including the FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time in which you will do so.

Please identify your notification with unique identifier: **CMS # 642688.**

Send your electronic response to ORAPHARM4_Responses@FDA.HHS.GOV with ATTN: CDR Steven E. Porter, Jr. or mail your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, CA 92612-2506

If you have questions regarding the contents of this letter, please contact LCDR Rumany Penn, compliance officer, at (949) 608-4409 or Rumany.Penn@fda.hhs.gov.

Sincerely,

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

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