U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

December 12, 2019

VIA UPS OVERNIGHT
Neil P. McGarvey, Pharm.D.
Co-Owner
Arnold Professional Pharmacy
1460 Ritchie Highway, Suite 103
Arnold, MD 21012-2704

Dear Dr. McGarvey:

From August 21, 2018, to September 5, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Arnold Professional Pharmacy, located at 1460 Ritchie Highway, Suite 103, Arnold, MD 21012-2704. During the inspection, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on September 5, 2018. FDA acknowledges receipt of your facility's response, dated September 26, 2018. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. 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 noted that your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products. In addition, your firm handled hazardous drug products without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent contamination. Specifically, your firm utilized non-dedicated equipment and utensils to produce hormone drug products with no assurance that your cleaning agent, (b) (4) , can deactivate and remove residual drug product.

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.

B. Corrective Actions

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

Regarding the insanitary condition observation in the Form FDA 483, your corrective action appears to be adequate. You have indicated that your standard practice has been and will continue to be using (b) (4) in non-sterile drug production.

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 [21 U.S.C. § 353a].

C. 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 the violations identified above 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 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 correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please address your (electronic) reply to:
Stephanie Durso
Director of Compliance
Office of Pharmaceutical Quality Operations, Division I
10 Waterview Blvd 3rd FL
Parsippany, NJ 07054
Email: ORAPHARM1_RESPONSES@fda.hhs.gov

If you have questions regarding the contents of this letter, please contact James Mason, Compliance Officer by phone at 570-262-0519 or by email at james.mason@fda.hhs.gov.

Sincerely,

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300092363, cn=Craig W. Swanson -S
Date: 2019.12.12 14:31:24 -05'00'

Diana Amador-Toro
Program Division Director
Office of Pharmaceutical Quality Operations, Division I