U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

EMAIL DELIVERY
RETURN RECEIPT REQUESTED

July 20, 2022

Renee T. McCarthy, PharmD
Owner and Pharmacist-in-Charge
Valgene Incorporated dba Cape Drugs
1384 Cape St Claire Rd
Annapolis, MD 21409-5325

Dear Dr. McCarthy:

From November 8, 2021 to December 2, 2021, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Valgene Incorporated dba Cape Drugs, located at 1384 Cape St Claire Rd, Annapolis, MD 21409. During the inspection, the investigators noted deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

FDA issued a Form FDA 483 to your firm on December 2, 2021. FDA acknowledges receipt of your facility's response, dated December 22, 2021. We also acknowledge that on December 3, 2021, you initiated a voluntary recall of certain lots of methylcobalamin 12mg/ml injection, 1 mL vials, and B-complex, injection, 1 mL vials due to lack of processing controls.

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 investigators 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 investigators observed that:

1. The ISO 5 classified aseptic processing areas had difficult to clean and particle-generating equipment or surface. During the inspection investigators noted that the ISO 5 classified laminar airflow hood (LAFH) sits atop a bench which appears to be made of a wood-like material laminated on the top and sides. The bottom of the bench is not laminated, and the wood-like material is exposed within the ISO 7 classified "Sterile Prep" buffer room.

2. Your facility design allowed the influx of poor-quality air into a higher classified area. Your firm uses (b) (4) , that are located between your unclassified hallway and your ISO 7 classified buffer rooms, to exchange production materials used in the production of sterile products. Use of these (b) (4) permit unclassified air to enter the ISO 7 classified area.

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 response related to the insanitary conditions observed at your facility, we cannot fully evaluate the adequacy because you did not include sufficient information or supporting documentation:

1. In regard to the bench which appears to be made of a wood-like material, you stated that you stopped the compounding of sterile products in the affected ISO room and committed to replace the hood/bench area. We also recognize that you conducted a voluntary recall of the observed compounded products during the FDA inspection. However, you have not provided evidence for the replacement of the bench, the current configuration of hoods in the affected ISO room, nor have you conducted a product impact investigation regarding previously compounded products under insanitary conditions.

You did not address certain observations related to insanitary conditions, for example:

1. Regarding the use of a (b) (4) from your unclassified hallway into ISO 7 classified buffer rooms, you stated that there are controls in place to avoid free flow of non-controlled air to enter the ISO compounding rooms by having (b) (4) process which allow for only one door to be open at once. You do not maintain the (b) (4) under ISO 7 conditions to ensure that contamination is not introduced into the ISO 7 classified buffer rooms through material flow or provide evidence of additional controls that mitigate the risk associated with the material flow. FDA is concerned that your current practice of passing materials and components from the unclassified areas directly into the ISO 7 classified rooms poses a risk of introducing contamination that could adversely affect the environmental controls and by extension the quality of the drug products compounding by your firm.

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 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 send your electronic response to ORAPharm1_Responses@fda.hhs.gov and include as a reference FEI# 3004562873.

If you have questions regarding the contents of this letter, please contact Compliance Officers, Jose O. Hernandez-Guzman (jose.hernandez-guzman@fda.hhs.gov) and Liatte Closs (liatte.closs@fda.hhs.gov).

Sincerely,

Nerizza B. Guerin -S

Digitally signed by Nerizza B. Guerin -S
Date: 2022.07.20 10:57:08 -04'00'

Nerizza Guerin
Acting Program Division Director/District Director
U.S. Food and Drug Administration OPQO Division I / New Jersey District