Renee McCarthy, PharmD
Owner, Compounding Specialist

August 31, 2022

VIA ELECTRONIC MAIL ORAPharm1_Responses@fda.hhs.gov
and First Class Mail

Nerizza B Guerin, Acting Program Division Director/District Director
U.S. Food and Drug Administration OPQO Division I / New Jersey District
10 Waterview Blvd.
3rd Floor
Parsippany, NJ 07054

RE: Valgene, Incorporated dba Cape Drugs ("Cape Drugs") Response to FDA Untitled Letter dated 07/20/2022
FEI# 3004562873

Dear Acting Director Guerin:

Cape Drugs would like to take this opportunity to respond to the inspectional observations listed on the recent letter issued by the New Jersey District Office on July 20, 2022 ("Untitled Letter") to provide the Food and Drug Administration ("FDA") with further assurance that Cape Drugs is committed to providing the safest and highest quality compounded preparations to their patients.

Cape Drugs takes FDA's observations and its professional responsibilities very seriously. Patient safety and well-being are the primary concerns of Cape Drugs. Cape Drugs strives to and does provide the highest quality preparations and services. Cape Drugs has been under new management for nearly 6 years and we have implemented rigorous quality assurance and standard operating procedures ("SOPs") designed to comply with applicable requirements and produce high-quality compounded sterile preparations.

As an initial matter, we also note that the pharmacy fully and voluntarily cooperated with FDA throughout the course of this matter. The pharmacy did not refuse to provide any information.

Further, and in response to FDA's observations, Cape Drugs implemented several immediate corrections to certain compounding practices and procedures. Those corrections included updating various SOPs and enhancing other procedural aspects of Cape Drugs operations. Cape Drugs took these, and the other steps set forth herein to ensure that it continues to meet recognized standards applicable to Maryland State Board of Pharmacy regulations, USP standards, as well as FDA guidance applicable under FDCA Section 503A, so that patients can continue to access high-quality compounded medications.

Please note that this Response to FDA's Untitled Letter does not constitute an admission or agreement by Cape Drugs to the alleged deficiencies or conclusions set forth in FDA's Letter. None of the actions that may be taken by Cape Drugs pursuant to its response should be considered an admission that an Observation existed or that additional

measures should have been in place at the time of the inspection. Without conceding that any of the Observations are applicable, set forth below are FDA's Observations, followed by Cape Drugs response thereto.

Cape Drugs respectfully requests that if FDA posts the Untitled Letter issued to this pharmacy, then FDA shall post this Response along with it, and also provide this Response when FDA provides the Untitled Letter to third parties.

As such, Cape Drugs provides the following response to the Untitled Letter:

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.*

As was stated in Cape Drugs 483 Response, the compounding room containing the old bench ceased being used until such time as a new hood/bench was installed and certified. The new LAFH/bench was ordered on (b) (4) and was delivered on (b) (4). It is scheduled to be certified on (b) (4) and will be put into operation at that time. The old hood/bench has been removed from Cape Drugs. The new LAFH/bench is a (b) (4) (b) (4) made by (b) (4). See Attachment 1 for a description of the new LAFH/bench and Attachment 2 for a copy of the invoice related to its purchase.

Cape Drugs believes that the voluntary recall and additional actions taken as described in this Response and the 483 Response previously submitted adequately address concerns of compounding 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) (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.*

As stated in Cape Drugs 483 Response, these (b) (4) are (b) (4), which allows only one of the box doors to be opened at a time. In no instance can both box doors be open at the same time. Items are wiped down with (b) (4) prior to being placed in the (b) (4). The (b) (4) are also gasketed, and since the ISO 7 buffer rooms are under positive pressure, no air from inside the (b) (4) should come into the buffer rooms when opened. Included as Attachment 3 is our most recent certification report showing that

these rooms are operated under positive pressure. We have also included in Attachment 4 copies of the Viable sampling and surface sampling of the (b) (4) done in Feb 2021 that demonstrate NO growth of either Surface sample or Air sampling done at the time in the (b) (4) or elsewhere in the compounding areas. These tests are always conducted as part of (b) (4) certification of the clean rooms.

Additionally, Cape Drugs has enlisted the assistance of a qualified consultant, knowledgeable in industry standards for sterile compounding, to review the processes being utilized at Cape Drugs.

Sincerely,

Renee McCarthy

Renee T. McCarthy, Pharm D., Owner
Valgene Incorporated dba Cape Drugs