



Renee McCarthy, PharmD
Owner, Compounding Specialist

November 3, 2022
VIA ELECTRONIC MAIL

José O. Hernández, CSO / Compliance Officer
Office of Pharmaceutical Quality Operations, Division I (VT, NH, ME, MA, CT, RI, NY, NJ, PA, DE, MD, D.C., VA, WV)
Office of Regulatory Affairs
U.S. Food and Drug Administration

RE: Valgene, Incorporated dba Cape Drugs ("Cape Drugs") Follow up to FDA Untitled Letter dated 07/20/2022
FEI# 3004562873 and Telephone Meeting on 11/1/2022

As per our discussion on 11/1/2022, Cape Drugs shall continue with its current process of using the ISO 7 Anteroom as the entry and exit point of all items that are transiting into and out of the ISO 7 Buffer rooms. For items entering, they shall be wiped with lint free wipes and sporicidal agent (b) (4) and allowed to dwell for at least (b) (4) before they are moved over the line of demarcation to the 'clean side' of the ISO 7 Anteroom. They shall be then be moved into the ISO 7 Buffer rooms where they shall be wiped again with (b) (4) and Sterile lint free wipes prior to entering the ISO 5 area (if applicable). Upon completion of compounding all items shall exit the ISO 7 Buffer area into the ISO 7 Anteroom and then exit the ISO 7 suite. This process has been included in the current Policy and Procedure (Sterile Compounding Area Cleaning and Disinfecting (02-04.01) Section XIX.

If at any point Cape Drugs chooses to resume use of the (b) (4) then (1) Additional studies such as Smoke Swirl testing shall first be conducted to confirm that potential contamination from the Non-classified space is not being introduced when the (b) (4) is opened and (2) The current Viable and Non -Viable Air Sampling Policy and Procedure (03-05.01) will be revised to include (b) (4) Air and Viable testing of (b) (4) and buffer rooms.

If you have any further questions please do not hesitate to contact me.

Sincerely,

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

Hours of Operation

M-F 9am – 6pm

Sat 9am – 3pm

Sun - Closed

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