PAVILION
COMPOUNDING PHARMACY, LLC
3200 Downwood Circle NW, Suite 210
Atlanta, Georgia 30327
Voice: 404-350-5780 Fax: 404-350-5640

December 9, 2020

On behalf of Pavilion Compounding Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's website. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21U.S.C. § 331(o), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Pavilion Compounding Pharmacy's Response dated December 9, 2020, excluding attachments/exhibits, to FDA's Untitled Letter dated November 6, 2020.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Pavilion Compounding Pharmacy and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Brad M. Cherson

Brad M. Cherson
Pharmacist-in-Charge
Pavilion Compounding Pharmacy, LLC
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VIA EMAIL

Case 605688

December 9, 2020

Monica R. Maxwell, Program Division Director
CC: Rebecca A. Asente, Compliance Officer
Department of Health and Human Services
Food and Drug Administration
60 Eighth Street NE
Atlanta, GA 30309

Re: Pavilion Compounding Pharmacy: Response to FDA Untitled letter dated November 6, 2020:
Case 605688

This letter is in response to the FDA Untitled Letter sent on November 6, 2020, regarding the corrective actions of Pavilion Compounding Pharmacy ("Pavilion") located at 3200 Downwood Cir. NW, Suite 210, Atlanta, GA 30327-1611. The corrective actions of Pavilion were submitted to the FDA in response to the issuance of FDA form 483 dated February 8, 2019. Pavilion's response to the FDA form 483 was submitted on February 27, 2019.

Set forth herein are Pavilion's Responses to FDA's Untitled Letter sent on November 6, 2020.

We look forward to continuing to work with the FDA to supply patients with the highest quality products as we continue to accommodate patient needs in our community. Over the past 20 years, Pavilion has always demonstrated a high standard of quality in patient care, and we welcome this opportunity to further improve upon these standards. If there are any questions or concerns in regards to our response, please contact me as soon as possible.

Respectfully,

Brad M. Cherson

Brad M. Cherson
Pharmacist-In-Charge
Pavilion Compounding Pharmacy, LLC
Response to Untitled Letter Dated November 6, 2020
Case 605688

Note: FDA Untitled Letter dated November 6, 2020 text is represented in ***Bold, Italic*** text.

We have reviewed your firm's response to the Form FDA 483, dated February 27, 2019. Examples of your corrective actions include:

> ***1. The preparation of hazardous drugs will be segregated in dedicated hoods using dedicated equipment.***
> ***2. Peridox RTU (oxidizing agent) will be used to clean between batches of hazardous drug products.***
> ***3. Personnel will wash hands and change gloves after the preparation of a batch of hazardous drugs products.***
> ***4. Gowns worn while preparing hazardous drugs will not be worn in other areas to avoid the potential spread of contamination and contaminated gowns will be changed immediately.***
> ***5. Personnel were trained in updated procedures and techniques related to the handling of hazardous drug products.***
> ***6. A layer of sealant was applied around the HEPA filter in the ISO 7 Anteroom to ensure a smooth surface.***
> ***7. Standard operating procedure (SOP) governing media fills was updated to reflect all aseptic operations, including syringe, vial, and ophthalmic bottle filling operations.***
> ***8. The preparation of intrathecal drug products was discontinued.***
> ***9. Finished drug products will not be dispensed from frozen stock solutions***.

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. Videos of the smoke studies that were performed under dynamic conditions were not provided.***
> ***2. You stated that polyolephin alpha (PAO) was used to perform the smoke studies. PAO is not suitable for use in smoke studies because it leaves residues that are difficult to clean. PAO is typically used for HEPA filter leak testing and is not used to generate smoke for airflow visualization studies.***

Pavilion Compounding Pharmacy Response to Untitled Letter:

Pavilion Compounding Pharmacy contracted with a new nationally accredited third-party certifier, EOC1 Environments of Care, in October 2019 to perform twice-yearly certification of the cleanrooms and both the hazardous and non-hazardous ISO 5 isolators. The certification process includes smoke visualization studies that are performed under dynamic conditions. Since Pavilion's response to FDA form 483, dated February 27, 2019, smoke visualization studies have been perform by the third party certifier under dynamic conditions on four (4) separate occasions. All of these smoke studies were performed under dynamic conditions, as shown in reports. These studies all indicated that, "during dynamic operating conditions the smoke demonstrates unidirectional airflow and sweeping action over and away from the simulated preparation" per USP 797 guidelines. However, the smoke visualization studies were not video recorded. Immediately upon receiving the Untitled Letter from the FDA, dated November 6, 2020, Pavilion contacted the third party certification company to request that the smoke visualization tests be completed again with video recordings. The recordings of the smoke visualization studies were completed November 12, 2020 (12 videos to be uploaded to flash drive and sent via mail). The pharmacist/operator in the video can be seen making multiple manipulations using vials, syringes, and ophthalmic bottles, representing dynamic conditions. This process is performed for all smoke visualization studies. Pavilion has additionally updated SOP 3.03, section 9.6.3, to state that all smoke visualization studies performed will be video recorded with each certification for documentation and training purposes.

In addition, Polyolephin alpha (PAO) is no longer used for smoke visualization studies. A previous third party certification company used PAO to perform smoke studies. However, Pavilion contracted with a different, nationally accredited and certified third party company, which has performed all clean room certifications, including smoke visualization studies, since Pavilion's response to FDA form 483 was submitted on February 27, 2019. All 4 of the smoke visualization tests were performed under dynamic conditions using a visual smoke that is neutrally buoyant and mimics ambient air. The third party certification company uses smoke generators that are highly controllable for accurate visualization of the smoke patterns.