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

February 27, 2019

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 web site. 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 February 28, 2019, excluding attachments/exhibits, to FDA's Form 483 dated February 8, 2019.

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
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VIA EMAIL

February 27, 2019

Monica R. Maxwell, Program Division Director
Jennifer L Huntington, Investigator
Department of Health and Human Services
Food and Drug Administration
60 Eighth Street NE
Atlanta, GA 30309

Re: Pavilion Compounding Pharmacy: Response to FDA Form 483 Observations: FEI No. 3004570352

This letter is in response to FDA Form FDA-483 Observations issued on February 8, 2019, regarding the inspection of Pavilion Compounding Pharmacy ("Pavilion") located at 3200 Downwood Cir. NW, Suite 210, Atlanta, GA 30327-1611. The inspection was conducted between February 4, 2019 through February 8, 2019. After this inspection, a FDA Form 483 was issued which includes five (5) observations.

Set forth herein are Pavilion's Responses to FDA's Observations. We respectfully request that this Response, excluding any attachments, be posted on the FDA's website, and provided every time a copy of Pavilion Compounding Pharmacy's FDA Form 483 is provided to an entity outside of the FDA.

Pavilion Compounding Pharmacy is committed to adhering to the applicable laws and regulations that ensure patient safety and the preparation of high-quality compounded formulations. As a Section 503A pharmacy, Pavilion Compounding Pharmacy is currently licensed and in good standing with the Georgia Board of Pharmacy and complies with all Georgia Rules and Regulations. Medications are compounded and dispensed based on the receipt of individual prescriptions from a licensed provider. Pavilion Compounding Pharmacy also complies with applicable United States Pharmacopoeia chapters <795> and <797> on pharmacy compounding.

We look forward to working together with 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 Form 483 Letter Dated February 8, 2019

Note: FDA Form 483 text is represented in ***Bold, Italic*** text.

OBSERVATION 1

You produced hazardous drugs without providing adequate containment, segregation and cleaning of personnel to prevent cross-contamination.

Specifically, hormone and non-hormone containing drugs are prepared in your negative pressure, non-sterile room without any gowning controls or cleaning procedures in place to prevent cross-contamination between batches. On 02/04/2019, I observed the production of Testosterone LD Topical 8mg/mL Cream (lot 02042019@22) and BIEST (80:20)/Prog LD Topical 3/30mg/GM Cream (lot 02042019@23) in the same area as non-hazardous Bleach-Ease (Nourivan) 8% Cream (lot 02042019@1).

Response to Observation 1:

Pavilion Compounding Pharmacy has updated its standard operating procedure (SOP), SOP 7.01, and the relevant staff have been trained (Attachment 1), to provide adequate hazardous drug containment, segregation and cleaning of personnel to prevent cross-contamination between batches. The updated SOP requires all hazardous drugs to be compounded in dedicated, externally vented hood(s) located within a negative pressure, externally vented non-sterile or sterile laboratory, when applicable. Dedicated equipment will be used for all hazardous drugs that are separate from equipment used to compound non-hazardous drugs. After each batch of hazardous drug compounded, cleaning procedures as described in SOP 7.01 will be performed using a studied decontamination and disinfection solution (PeridoxRTU®) (Attachment 1). Personnel will change gloves between batches of hazardous drugs compounded and wash hands with a soap detergent. Gowns worn when handling hazardous drugs will not be worn to other areas in order to avoid spreading hazardous drug contamination and, per USP<800>, will be changed immediately if contaminated. Pavilion Compounding Pharmacy tested all compounding personnel who handle hazardous drugs with a manipulation technique test to examine competence in the containment, segregation and cleaning of hazardous drugs. (Attachment 2)

Date Effective: 2/19/2019

Completion Date: 2/19/2019

OBSERVATION 2:

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, a gap was observed in the ceiling of the ISO 7 ante room around the HEPA filter.

Response to Observation 2:

The investigator noted that a gap was observed in the ceiling of the ISO 7 anteroom around the HEPA filter. The ceiling tile in question did not appear to be loose or unsealed. A licensed cleanroom contractor also inspected the area in question, along with all ceiling tiles in the cleanroom, on February 13, 2019. The contractor found no loose or unsealed tiles or gaps in the ceiling allowing any outside intrusion of air into the rooms (Attachment 3). However, based on the investigator's observation, another layer of sealant was reapplied around the HEPA filter in the anteroom by the licensed contractor to ensure a smooth surface. Surface samples taken off the ceiling tiles around the HEPA filter and air samples using a volumetric air sampler were taken on February 12, 2019 and showed no growth via a third-party lab (Attachment 4). A third-party cleanroom certification company also completed non-viable particle counts on February 12th 2019, which showed all rooms met or exceeded ISO class 7 requirements (Attachment 4). Pavilion Compounding Pharmacy has updated SOP 3.02 (Attachment 5) to reflect that the cleanroom pharmacist will visually inspect ceiling tiles as part of the daily cleaning procedure, and training has been completed by all relevant staff as of February 11, 2019.

Observation 3:

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release

Specifically, your firm does not perform potency testing prior to release for non-sterile drug formulations. Examples include, but are not limited to the following non-sterile drug products:

- ***Cantharidin Plus Topical I% Liquid, Lot 01032019@75***
- ***Phenylephrine HCL/Lidocaine HCL Nasal 1 %/4% Solution, Lot 11282018@32***
- ***Phenylephrine 1 % Solution, Lot 05092018@45***

Response to Observation 3:

Pavilion Compounding Pharmacy is a state-licensed Section 503A pharmacy that is required to comply with applicable state laws and regulations governing pharmacy compounding, and with the applicable United States Pharmacopoeia chapters <795> and <797> on pharmacy compounding. Pavilion Compounding Pharmacy requests

to not be held to certain FDA current good manufacturing practice (cGMP) regulations applicable to outsourcing facilities and drug manufacturers. The prescriptions noted by the investigator in the Observation were written by licensed physicians who the pharmacist at the time believed were also the individually identified (and intended) patient for the compounded formulation. Pavilion Compounding Pharmacy has updated SOP 5.01 (Attachment 6) to revise the prescription receiving process, as a result of FDA's Observation. Pharmacists who receive a new prescription must ensure the prescription is in fact for an individually identified patient. Specifically, for example, if a physician writes a prescription for him or herself, then the pharmacist will notate on the prescription after confirming with the prescriber that the prescription is intended for personal use only (i.e., for the individually identified patient). The pharmacist also will make reasonable efforts to check the quantity prescribed, the intended dose, and use for the condition being treated to confirm that such a prescription is reasonable for personal use. Training on revised SOP 5.01 was completed by all pharmacists February 25, 2019 (Attachment 6).

Date Effective: 2/25/2019

Observation 4:

Batch production and control records do not include complete information relating to the production and control of each batch

Specifically, your firm's formula worksheets do not include the following information for non-sterile drug products:

- ***Identity of major equipment used***
- ***Laboratory results***
- ***Inspection of packaging and labeling***
- ***A statement of actual yield***
- ***Specimens of labeling***

Example include, but are not limited to the following:

- ***Cantharidin Plus Topical I% Liquid, Lot 01032019@75***
- ***Phenylephrine HCL/Lidocaine HCL Nasal 1%/4% Solution, Lot 11282018@32***
- ***Phenylephrine 1% Solution, Lot 05092018@45***

Response to Observation 4:

Pavilion Compounding Pharmacy is a state-licensed Section 503A pharmacy that is required to comply with applicable state laws and regulations governing pharmacy

compounding, and with the applicable United States Pharmacopoeia chapters <795> and <797> on pharmacy compounding. Pavilion Compounding Pharmacy requests to not be held to certain FDA current good manufacturing practice (cGMP) regulations applicable to outsourcing facilities and drug manufacturers. The prescriptions noted by the investigator in the Observation were written by licensed physicians who the pharmacist at the time believed were also the individually identified (and intended) patient for the compounded formulation. Notwithstanding, SOP 9.04 (Attachment 10) has been updated to include the laboratory results, identity of major equipment used, inspection of packaging and labeling, and a statement of the actual yield on the formula worksheet. Training of relevant staff was completed on February 25, 2019, and sample formula worksheets attached (Attachment 10).

Pavilion Compounding Pharmacy has updated SOP 5.01 (Attachment 6) to revise the prescription receiving process, as a result of FDA's Observation. Pharmacists who receive a new prescription must ensure the prescription is in fact for an individually identified patient. Specifically, for example, if a physician writes a prescription for him or herself, then the pharmacist will notate on the prescription after confirming with the prescriber that the prescription is intended for personal use only (i.e., for the individually identified patient). The pharmacist also will make reasonable efforts to check the quantity prescribed, the intended dose, and use for the condition being treated to confirm that such a prescription is reasonable for personal use. Training on revised SOP 5.01 was completed by all pharmacists February 25, 2019 (Attachment 6).

Date Effective and Completed: 2/25/2019

Observation 5:

Procedures designed to prevent insanitary conditions are not established or followed

Specifically,

A) Media fills are not representative of all routine aseptic operations. For example, media fills are not performed for vial filling operations. For example, your firm produced Glutathione Solution 200mg/mL injectable, Lot 01292019@18 which was produced in a vial.

B) There is no documentation or evidence to show that smoke studies are performed under dynamic conditions in your hazardous and non-hazardous ISO 5 glove boxes.

C) Your firm does not perform endotoxin testing for each lot of intrathecal drug product prepared. For example, your firm produced Morphine Sulfate (PF) 20mg/mL injectable, Lot 01312019@1 for intrathecal use however there was no endotoxin testing performed prior to release for use.

D) Your firm has no evidence that filter integrity testing on filters were performed when dispensing finished drug products from stock solutions. For example, your firm produced Vitamin B Complex 100 injectable, Lot 10292018@10, BUD 12/13/18 in a bulk syringe which was then frozen. The drug product was thawed for the filling o (b) (6) ***on 11/05/18, refrozen, and thawed again on 11/13/18 for the filling o*** (b) (6) ***There are no formula worksheets documenting the filling, filtration, and filter integrity testing of*** (b) (6) ***and*** (b) (6)

Response to Observation 5:

A). USP <797> states that media fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated. Our organization is informed and believes that USP <797> guidelines were met with our current media fill program even though media fills were not performed for vial filling operations. Notwithstanding, SOP 9.11(Attachment 7) has been updated to reflect all aseptic operations, including vial filling operations. All sterile containers used in aseptic operations, including sterile syringes, vials, and ophthalmic bottles, will be used in media fills for compounding personnel. Training on revised SOP 9.11 was completed by all relevant staff on February 11, 2019 (Attachment 7). The maximum batch size for each sterile container used will also be reflected in media fills. Media fills were completed using our new procedure on February 11, 2019 for all sterile compounding personnel. (Attachment 8)

Date Effective and completed: 2/11/2019

B). Smoke studies were performed under dynamic conditions during the last cleanroom certification, and are performed twice yearly during re-certification in both hazardous and non-hazardous ISO 5 isolators. However, this was not clearly stated on the documentation form provided by the third-party certifier (as noted by the investigator). A third-party certification company performed smoke studies again on February 12, 2019, under dynamic conditions, in both the hazardous and non-hazardous ISO 5 glove boxes. As noted in the attached report, unidirectional airflow was observed under dynamic conditions and no significant turbulence or stagnant air flow was observed while making multiple aseptic manipulations that represented all compounding processes. (Attachment 9).

Date completed: 2/12/2019

C). As a Section 503A compounding pharmacy, Pavilion Compounding Pharmacy follows the USP <797> guidelines for bacterial endotoxin testing. Specifically, we test for bacterial endotoxins based on the following USP <797> guideline: All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are

sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins. Since intrathecal drug products are by nature a patient-specific prescription, they are produced in batch sizes of one unit.

Due to the batch size of "one" and the USP <797>-determined 72-hour shelf life for the product, it is neither economically nor otherwise feasible to test each finished intrathecal drug product for endotoxins. **Therefore, Pavilion Compounding Pharmacy has decided to no longer compound intrathecal products.**

Date effective: February 28, 2019

D). The process of freezing, thawing, and refreezing a "stock" solution for use in compounding, as described in FDA's Observation, has been discontinued, effective February 8, 2019 (as discussed with the investigator during the inspection). All products will be compounded and placed in the final sterile container used for dispensing at the same time the product is compounded. This will be reflected on the formula worksheet for each batch. The formula worksheets will include documentation of the filling, filtration, and filter integrity testing for each compounded formulation. A formula worksheet will be created for each and every compound made. SOP 9.04 has been updated to reflect these changes and relevant staff were trained on February 25, 2019. Sample formula worksheets are attached (Attachment 10).

Date Effective: February 8, 2019