Malley's Compounding
PHARMACY

March 4, 2021

Maria Kelly-Doggett
Compliance Officer
Office of Regulatory Affairs (ORA)
Office of Pharmaceutical Quality Operations, Division IV
U.S. Food and Drug Administration

Ms Kelly-Doggett:

On behalf of Columbia River Pharmacy DBA Malley's 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, 21 U.S.C. § 331, 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: Columbia River Pharmacy's letter dated September 4, 2019 excluding attachments/exhibits, which responds to FDA's Form 483 dated August 16,2019.

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 Columbia River Pharmacy and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Respectfully,

Anne Henriksen, PharmD

Anne Henriksen, Pharm.D.
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Malley's Compounding Pharmacy
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September 4, 2019

Miriam Burbach, District Director
Food and Drug Administration
22215 26th Avenue SE, Ste 210
Bothell, WA 98021

Dear Director Burbach:

The Food and Drug Administration (FDA) conducted an inspection of Columbia River Pharmacy, DBA Malley's Compounding Pharmacy, from August 12, 2019 to August 16, 2019. Please accept this letter as the Pharmacy's response to the observations raised in the FDA Form 483. We respectfully request that this response be posted on the FDA's website with the Form 483 and be included every time the FDA provides a copy of the Form 483 to any individual or entity outside the FDA.

To the extent the observations cited in the Form 483 are based on the current Good Manufacturing Practices (cGMPs) for finished pharmaceuticals, such observations are inapplicable to the operations of the Pharmacy. Additionally, to the extent the observations cited in the Form 483 are based on USP <800>, which does not become effective until December 1, 2019, such observations are also inapplicable to the current operations of the Pharmacy.

The Pharmacy operates in compliance with the requirements of 21 U.S.C. § 353a, applicable state laws and regulations governing pharmacy compounding, and with the United States Pharmacopoeia USP chapter <795>. The Pharmacy does not compound any sterile or office-use preparations.

With this response, the Pharmacy has sought to address the FDA's observations and concerns. While cGMP requirements are not applicable to the Pharmacy's operations and USP <800> standards are not currently enforceable, we have accepted the FDA's observations as suggestions for improvement and have implemented additional best practices to the extent feasible and compatible with our obligations under state law and the USP guidelines.

The FDA Form 483 observation 1 states as follows:

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination. Specifically,

A. Hazardous bulk drug substances (ie: hormones) are stored together with non-hazardous bulk drug substances within your compounding lab.

B. A deactivating agent is not used to clean non-dedicated equipment (ie: hoods and utensils) to prevent cross contamination.

C. Non-dedicated powder containment hoods are designed in a way that the exhaust is vented back into the compounding room.

D. Glassware (ie: graduated cylinders, mortar and pestles) is stored on open shelves by the end of the compound lab with no door present.

In response to observation 1A: The pharmacy is compliant with USP <795> guidelines. Current USP <795> guidelines do not require hazardous and non-hazardous drugs to be stored separately in a compounding lab. This requirement is only addressed in USP <800>, which does not become effective until December 1, 2019. The Pharmacy operates in compliance with the requirements of 21 U.S.C. § 353a, applicable state laws and regulations governing pharmacy compounding, and with the United States Pharmacopoeia USP chapter <795>. In an effort of continued quality improvement, the Pharmacy has updated the list of hazardous drugs (HD). Please see updated SOP 14.008 *Hazardous Drugs List- Composite List.* Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

While the pharmacy is working toward USP <800> implementation, the storage of HD bulk drug substances is addressed in updated SOP 14.405 *Storage and Handling of HDs.* In accordance with this SOP, anti-neoplastic and HD active pharmaceutical ingredients (APIs) will be stored in a USP <800> compliant room no later than December 1, 2019. While the transition to this room is being finalized, this SOP allows anti-neoplastic and HD APIs to be stored in a clearly defined location in the compounding lab. This storage is located off the floor and away from equipment, utensils, and non-HD APIs. This area is away from work spaces and employees are trained to not approach the storage area of HD APIs unless specifically entering the area to obtain an API for a compounded preparation. Training documentation can be found is SOP 2.002 *Documentation of Employee Training.*

To reduce the risk of cross-contamination, bulk drug substance containers have been cleaned with isopropyl alcohol and non-linting cloth upon entry and exit of the powder containment hood according to SOP 8.086 *Cross-Contamination Prevention.* Training documentation can be found in SOP 2.002 *Documentation of Employee Training.* In an effort of continuous quality improvement, bulk drug substance containers are now

deactivated with sodium hypochlorite applied with a non-linting cloth then cleaned with isopropyl alcohol applied with a non-linting cloth upon exit of the powder containment hood as per SOP 14.405 *Storage and Handling of HDs.* Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

The Pharmacy is actively working on implementing USP <800> standards. This includes moving the compounding of all hazardous drugs to a negative pressure room. The modular room exists within the Pharmacy. The pharmacy is actively working with the manufacturer of the room to ensure that it meets all USP <800> requirements on or before December 1, 2019. Upon completion, all hazardous bulk chemicals will be moved into the USP <800> modular room as detailed in updated SOP 14.405 *Storage and Handling of HDs.* Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

In response to Observation 1B: The Pharmacy is compliant with current USP <795> guidelines. Current USP <795> guidelines do not address the use of a deactivating agent. Deactivating agents are addressed in USP <800>, which does not become effective until December 1, 2019. The Pharmacy has had the practice of using isopropyl alcohol and a non-linting cloth to clean equipment including hoods and utensils before and after making every compounded medication according to SOP 8.086 *Cross-Contamination Prevention.* Training documentation can be found in SOP 2.002 *Documentation of Employee Training.* The Pharmacy has implemented using sodium hypochlorite to serve as a deactivating agent. This change was made during the week of the inspection and is currently in practice. See updated SOP 14.425 *Equipment and Utensils For Use With Hazardous Drugs*, which address the cleaning and storage of HD equipment. Additionally, updated SOP 4.03 *Powder Hood Use and Maintenance*, addresses the deactivation of hoods with sodium hypochlorite and updated SOP 14.405 *Storage and Handling of HDs* details the deactivation of bulk drug substance containers with sodium hypochlorite. Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

In response to Observation 1C: The Pharmacy is compliant with current USP <795> guidelines. USP <795> allows for the exhaust of powder containment hoods to be vented back into the compounding room. USP <800> addresses additional requirements for the exhaust from powder containment hoods. Such requirements do not become effective until December 1, 2019. The Pharmacy has plans to purchase a powder containment hood with double HEPA filters on or before December 1, 2019 for use within the modular USP <800> compounding room.

In response to Observation 1D: The Pharmacy is compliant with current USP <795> guidelines. In an effort of continuous quality improvement and before the inspection was over, the pharmacy had moved all glassware to a cabinet with doors. Please see updated SOP 6.001 *Glassware- Cleaning and Storage,* which outlines the appropriate storage of glassware. Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

an effort of continuous quality improvement, the Pharmacy plans to install a door in the open doorway. We anticipate the instillation of this door by September 30, 2019. Please see updated SOP 4.001 *Air Temperature and Humidity Control and Monitoring*, which prohibits the use of fans in the compounding lab. Training documentation can be found in SOP 2.002 *Documentation of Employee Training.*

The Pharmacy staff has been retrained on the SOP's referenced in this letter. SOP training takes place on an annual basis, and more frequently when changes occur or additional training is required. Please see SOP 2.002 *Documentation of Employee Training,* which details SOP training requirements and documentation.

We trust that the information provided above will resolve each of the observations noted in the FDA Form 483. If lingering concerns exist, or if we can provide any additional information or documentation that would be helpful to the FDA in evaluating the Pharmacy's non-sterile compounding operations, please do not hesitate to let us know so that we may supplement this response accordingly.

Sincerely,

Anne Henriksen Pharm.D.

Anne Henriksen, Pharm.D.
Owner- Pharmacist in Charge
Malley's Compounding Pharmacy