August 1, 2017

Gordon MacDonald, RPh
Supervising Pharmacist Investigator
Washington State Department of Health
Pharmacy Quality Assurance Commission
PO Box 47852
Olympia, Washington, 98501

Dear Mr. MacDonald:

The purpose of this letter is to refer to the Washington State Department of Health (DOH) for appropriate follow up, regarding the U.S. Food and Drug Administration's (FDA) concerns about the sterile practices observed during an FDA inspection at a pharmacy licensed by the Washington DOH, University of Washington Medical Center Inpatient Pharmacy, located at 1959 NE Pacific St, PO Box 356015, Seattle, Washington, 98195-6015. (Pharmacy License Hospital #PHAR.CF.00001058-HOSP).

FDA inspected the firm from July 11, 2016, to August 4, 2016. Washington DOH was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM519345.pdf, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, [which contains additional information about our inspection]. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by University of Washington Medical Center Inpatient Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes. In the firm's response to the Form FDA 483, dated August 24, 2016, the firm advised FDA that it produces "compounded sterile preparations used for identified patients and produced pursuant to valid orders."

During the inspection, the FDA investigators observed deviations from appropriate sterile

practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The failure to consistently use sterile wipes in the ISO 5 hoods, to disinfect materials and components at each transfer into locations with higher classified air, and to wipe down depyrogenated glassware.
2. Employees with facial makeup engaged in the production of aseptically produced drug product.
3. The presence of wood doors within the small clean room.
4. The lack of dynamic smoke studies for the ISO 5 hoods.
5. The presence of a white residue on the HEPA filter grate cover within one (1) ISO 5 hood in the small clean room.
6. The use of non-sterilized glassware by the drug service laboratory to prepare aseptically filtered drug products.

University of Washington Medical Center Inpatient Pharmacy committed to FDA in its responses to the Form FDA 483, dated August 24, 2016, and February 28, 2017, to correct the deviations in the Form FDA 483, and provided documentation in support of the corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Washington State DOH for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Maria P. Kelly-Doggett, Compliance Officer, at (425) 302-0427, or by email at maria.kelly-doggett@fda.hhs.gov.

Sincerely,

CDR Steven E. Porter, Jr.
Los Angeles District Director

SP: mpk

cc: Shabir M. Somani, MS, MBA, RPh, Chief Pharmacy Officer
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