UNITED PARCEL SERVICE
SIGNATURE REQUIRED

May 23, 2017

Kamlesh Gandhi
Executive Director
Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005-8520

Dear Mr. Gandhi:

The purpose of this letter is to refer to the Arizona State Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Arizona BOP, MFP Limited, dba Prescription Lab Compounding Pharmacy, located at 6586 E. Grant Road, Tucson, AZ 85715 (Pharmacy license #Y003173).

FDA inspected the firm from August 31, 2015, to September 10, 2015. FDA investigators were accompanied by an Arizona state Compliance Officer on August 31, 2015, and September 3, 2015. A redacted 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/UCM467205.pdf

During the inspection, the FDA investigators noted that Prescription Lab Compounding Pharmacy produced and dispensed domperidone products.

During the inspection, the FDA investigators also observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. An example of a deviation observed during our inspection:
Equipment used to mix drug product components prior to the sterilization step are not protected from contamination. They were observed stored on a rack, uncovered, in the ISO 8 room after depyrogenation.

FDA issued a Warning Letter to the firm on November 16, 2016. A copy of the Warning Letter can be found at:
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm530474.htm). In its response to the Warning Letter, which FDA received on December 2, 2016, the firm advised FDA that the observed deviation "was corrected before the end of the inspection" and "has not

occurred again." The firm also advised FDA that on November 6, 2016, it had "ceased all compounding and dispensing of domperidone" and that it had "absolutely no plans to compound or dispense domperidone again." After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm has apparently ceased production of domperidone and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Arizona State BOP 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 Jessica Mu, Compliance Officer, at (949) 608-4477, or by email at Jessica.mu@fda.hhs.gov.

Sincerely,

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

SP: jm