U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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August 9, 2017

Steven W. Schierholt, Esq.
Ohio State Board of Pharmacy
Executive Director
77 South High Street, 17th Floor, Room 1702
Columbus, OH 43215-6126

Dear Mr. Schierholt:

The purpose of this letter is to refer to the Ohio 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 Ohio BOP, Central Admixture Pharmacy Services (CAPS Cleveland) 8300 Sweet Valley Drive, Valley View, OH 44125 (Specialty Pharmacy Category Two, SP021312700-02).

FDA inspected the firm from October 26, 2015, to January 21, 2016. The Ohio State BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM487831.pdf .

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by CAPS Cleveland 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, received February 10, 2016, CAPS Cleveland advised FDA that it "only compounds drugs for identified individual patients based on the receipt of valid prescriptions and also satisfies the other requirements of section 503A."

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. For example, media fills were not performed under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations. CAPS committed to FDA in its response to the Form FDA 483, received February 10, 2016, and April 12, 2016, to correct the deviations described in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

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 apparently obtains prescriptions for identified individual patients, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Ohio 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 Tina M. Pawlowski, Compliance Officer, at 313-393-8217, or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Art O. Czabaniuk
Division Director
Division of Pharmaceutical Quality Operations III