



**VIA UPS**

Food and Drug Administration  
Detroit District  
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Detroit, MI 48207  
Telephone: 313-393-8100  
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March 22, 2017

Linda Clewley, Manager  
State of Michigan, Department of Licensing and Regulatory Affairs (LARA)  
Bureau of Professional Licensing, Board of Pharmacy  
525 West Allegan Street  
Lansing, Michigan 48933

Dear Ms. Clewley:

The purpose of this letter is to refer to the State of Michigan, Department of Licensing and Regulatory Affairs (LARA), Bureau of Professional Licensing, 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 state of Michigan, Central Admixture Pharmacy Services, Inc. (CAPS), located at 37497 Schoolcraft Road, Suite 200, Livonia, Michigan 48150 (Pharmacy # 5301006720).

FDA inspected the firm from November 16, 2015, to December 4, 2015. The Michigan 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/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm485492.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by CAPS, Livonia location 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 response to the Form FDA 483, received December 30, 2015, the firm advised FDA that it prepares "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. Examples of deviations observed during our inspection include:

1. The firm did not adequately disinfect non-sterile materials and components prior to transferring them from the ISO 7 into the ISO 5 workstation.

2. During aseptic production, operators were observed blocking first air with gloved hands during aseptic production.

CAPS committed to FDA in its responses to the Form FDA 483, dated December 28, 2015, and April 12, 2016, to correct the deviations in the Form FDA 483. 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 Michigan 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](mailto:tina.pawlowski@fda.hhs.gov).

Sincerely,



Art O. Czabaniuk  
District Director  
Detroit District Office