



Philadelphia District  
US Customs House, Room 900  
200 Chestnut Street  
Philadelphia, PA 19106

Telephone: (215) 597-4390  
FAX: (215) 597-4660

January 17<sup>th</sup>, 2017

Melanie Zimmerman  
Executive Secretary  
Pennsylvania State Board of Pharmacy  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman:

The purpose of this letter is to refer to the Pennsylvania 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 Pennsylvania BOP, Central Admixture Pharmacy Services, Inc. (CAPS Philadelphia), located at 253 Gibraltar Road, Horsham, Pennsylvania 19044 (Pharmacy # [PP414952L](#)).

FDA inspected the firm from November 9, 2015, to November 20, 2015. FDA investigators were accompanied by Pennsylvania state investigators for 8 days. 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/ucm477750.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by CAPS Philadelphia 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, dated December 15, 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 ISO 5 area had visible corrosion on the brackets that support bars used to hold IV

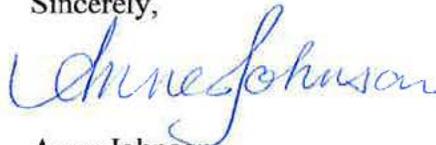
- bags. The observed corrosion included rust and chipped paint.
2. Personnel involved in aseptic operations were observed reusing gowns that were hanging in the ISO 8 gowning room, on a rack with visible filth.

Central Admixture Pharmacy Services committed to FDA in its responses to the Form FDA 483, dated December 15, 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 Pennsylvania 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 Yvette Johnson, Compliance Officer, at 215-717-3077, or by email at [Yvette.Johnson@fda.hhs.gov](mailto:Yvette.Johnson@fda.hhs.gov).

Sincerely,

A handwritten signature in blue ink that reads "Anne Johnson". The signature is written in a cursive style with a large, flowing "A" and "J".

Anne Johnson  
District Director  
Philadelphia District Office