



VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

February 15, 2017

Erica White, Executive Director
Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258

Dear Ms. White:

The purpose of this letter is to refer to the Florida 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 Florida BOP, Absolute Pharmacy, LLC, 16011 N. Nebraska Avenue, Suite 103 Lutz, FL 33549. (Sterile compounding # PH28269 and community pharmacy # PH28122; expires: February 28, 2017).

FDA inspected the firm from March 21, 2016, to April 11, 2016. FDA investigators were accompanied by Florida state investigators for 2 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/ucm501390.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Absolute 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.

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 failed to disinfectant equipment prior to introduction into the aseptic processing area. For example, the firm was observed introducing a pump into the ISO 5 hood without first disinfecting the pump and cord.
2. The firm failed to demonstrate through appropriate smoke studies that their ISO 5 buffer room is able to provide adequate protection to (b) (4) vials during the (b) (4) the ISO 5 hood (b) (4)
3. Personnel did not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during aseptic operations.

U.S. Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751
www.fda.gov

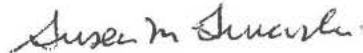
Absolute Pharmacy, LLC
Lutz, FL

Absolute Pharmacy, LLC committed to FDA in its response to the Form FDA 483, received May 4, 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 Florida 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 Andrea Norwood, Compliance Officer, at (407) 475-4724 or by email at Andrea.Norwood@fda.hhs.gov.

Sincerely,



Susan Turcovski
District Director
Florida District