DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

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VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

October 9, 2015

Allison Dudley
Executive Director
Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin# C04
Tallahassee, FL 32399-3254

Dear Ms. Dudley:

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 Ambient Healthcare of Central Florida, Inc., 202 SW 17th St., Suite C, Ocala, Florida (License # PH28323).

FDA inspected the firm from August 26, 2014, to September 15, 2014. A representative from the Florida Department of Health accompanied FDA on the inspection from August 26-27, 2014. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM430699.pdf.

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

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards. Although the deviations identified appear to be readily correctible, if not corrected, such practices could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The pharmacy technician was observed not sanitizing bags containing vials with sterile (b) (4) before placing them inside the ISO 5 hood during aseptic processing for sterile drug products;

2. The pharmacy technician was observed placing (b) (7) (C), (b) (6) bare hands on the outside of (b) (7) (C), (b) (6) sterile gown (e.g., the forearm section of the gown) while gowning to enter the ISO 7 area; and

3. The firm failed to demonstrate through appropriate studies that its hoods are able to provide adequate protection of the ISO 5 area in which sterile products are processed.

In the responses to the Form FDA 483, received by FDA on October 3, 2014 and April 17, 2015, Ambient Healthcare committed to correct the deviations in the Form FDA 483.

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, consistent with traditional pharmacy practice, 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,

for Susan M. Turcovski
Director, Florida District
Food & Drug Administration