DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Florida District
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VIA UPS
w/ DELIVERY CONFIRMATION

February 21, 2014

Mark Whitten
Executive Director
Florida Board of Pharmacy
4052 Bald Cypress Way, Bin #C04
Tallahassee, FL 32399-3254

Dear Mr. Whitten:

The purpose of this letter is to refer to the Florida 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, AnazaoHealth Corporation, located at 5710 Hoover Blvd, Tampa, FL 33634-5339.

FDA inspected the firm between February 19, 2013 and February 22, 2013. FDA's investigators were accompanied by personnel from the Florida Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics Program, on the first day of the inspection. Attached is a redacted copy of an FDA Form-483 that documents our investigator's observations from the inspection.

During the inspection, the investigators reviewed a small sample of records for products compounded by AnazaoHealth 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 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 does not perform adequate disinfection of the work surfaces within the aseptic processing areas. Investigators observed, and the firm confirmed, that bottles labeled "sterile" [redacted] (b) (4) are refilled with non-sterile [redacted] (b) (4) without obliterating the original "sterile" label of the bottle. These bottles were observed in the ISO-7 and ISO-8 areas of the nuclear and pain cleanrooms. It was not possible to

differentiate between bottles containing sterile [redacted] from those containing non-sterile [redacted] There is considerable risk of microbial contamination of the work surfaces for the ISO-5, ISO-7 and ISO-8 areas, with subsequent contamination of aseptically-produced sterile product, if non-sterile [redacted] is used to disinfect these areas instead of sterile [redacted]

2. The firm does not adequately verify the effectiveness of the [redacted] methods used to ensure that injectable products are sterilized.

3. The firm does not adequately verify the effectiveness of the methods for the sterilization and depyrogenation of vials and stoppers used to package sterile injectables.

4. The firm has not performed sterility testing on any finished sterile drug products. Sterility tests are performed only on samples taken from bulk stock solutions after [redacted], but before transfer into its final container closure system. This is inadequate because sterility can be compromised during transfer to the final container.

AnazaoHealth Inc. committed to FDA in its March 7, 2013, response to the Form FDA 483 to correct some of the deviations.

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. In addition, the deviations identified appear to be readily correctable, and the firm has agreed in writing to correct some of the deviations. Therefore, FDA believes that the corrective actions can be appropriately overseen by the State, and 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,

Elizabeth W. Ormond
Acting Director, Florida District