DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
8050 Marshall Drive, Suite 205
Lenexa, Kansas 66214-1524

Telephone: (913) 495-5100

February 26, 2014

Kimberly A. Grinston, JD
Executive Director
Missouri Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625

Dear Ms. Grinston:

The purpose of this letter is to refer to the Missouri 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 Missouri BOP, Foundation Care, LLC, located at 4010 Wedgeway Court, Earth City, MO, 63045-1213

FDA inspected the firm from March 11, 2013 to March 19, 2013. FDA's investigators were accompanied by a Missouri State BOP inspector for two days of the inspection. Attached is a redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Foundation Care 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. In the April 9, 2013 response to the Form FDA 483, the firm advised FDA that "All compounded products are prescribed by a physician and dispensed directly to our patients. Foundation Care does not compound drugs for office use."[1]

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's viable and non-viable environmental monitoring program ensuring microbiological quality of the ISO 5 and 7 areas is inadequate. For example, the firm's environmental monitoring program does not include critical manufacturing equipment located in the ISO 5 area, nor does it specify the required frequency of sampling, or when

[1] See attached response letter dated April 9, 2013 from Daniel P. Blakely, RPh to Kansas City District Investigators.

samples are to be collected based on related activity in the compounding areas. In addition, the firm's program lacks scientifically based justification for the sample locations.

In its response, the firm committed to revise its viable and non-viable environmental monitoring program to include all equipment contained in the cleanroom. However, in the revision the firm also changed their program testing requirement from [redacted] (b) (4) to [redacted] (b) (4) [redacted] We recommend that the environmental monitoring program be audited as part of the state's follow up activities including the adequacy of the frequency and time of sampling and evaluation of sample locations.

2. The firm does not conduct adequate qualification studies to assess whether proper particle control dynamics have been achieved throughout the ISO 5 area. For example, the firm has not conducted smoke studies since 2012.

3. The firm failed to record supplier lot numbers of TPN bags and ampules used in compounding of sterile drugs.

4. The investigator observed employee's using glassware for product waste and cleaning and then placing the glassware on tables where sterile compounding activities occur prior to cleaning the glassware adequately.

Foundation Care committed to FDA in its April 9, 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 Missouri 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 Danial S. Hutchison, Compliance Officer, at 913-495-5154, or by email at Danial.Hutchison@fda.hhs.gov.

Sincerely,

David Miser
Acting District Director
Kansas City District Office