DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 30, 2014

Kyle W. Parker
Executive Director
Ohio State Board of Pharmacy
77 S High St., Room 1702
Columbus, OH, 43215-6126

Dear Mr. Parker:

The purpose of this letter is to refer to the Ohio 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 Ohio BOP, Clinical Apothecaries, located at 4087 Medina Road, Medina, Ohio 44256.

FDA inspected the firm from November 6, 2013 to November 20, 2013 following receipt of an anonymous complaint. FDA investigators were accompanied by two Ohio State BOP inspectors for one day 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 investigator reviewed a small sample of records for products compounded by Clinical Apothecaries 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's program to ensure that each process used is able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

2. The firm does not adequately verify the effectiveness of the methods for the sterilization and depyrogenation of utensils and glassware used during aseptic operations.

3. The firm only performs sterility or endotoxin testing on a periodic basis with no established procedures for frequency and timeframes.

Clinical Apothecaries committed to FDA in its December 10, 2013, response to the Form FDA 483 to correct some of the deviations. [1] In addition, the deviations identified appear to be readily correctible.

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. In addition, the firm has agreed in writing to correct some of the deviations. Therefore, FDA is referring this matter to the Ohio 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 Stephen Rabe, Compliance Officer, at 513-679-2700, or by email at stephen.rabe@fda.hhs.gov.

Sincerely,

Paul Teitell
District Director
Cincinnati District Office

[1] See attached response letter dated December 10, 2013, from Jeffrey A. Potter to Paul Teitell, Cincinnati District Office, Director.