DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
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VIA UPS

September 09, 2016

Linda Clewley, Manager
State of Michigan, Licensing and Regulatory Affairs (LARA)
Bureau of Professional Licensing, Board of Pharmacy
525 West Allegan Street
Lansing, MI 48933

Dear Ms. Clewley:

The purpose of this letter is to refer Clark Professional Pharmacy, LLC, located at 3280 Washtenaw Ave., Ann Arbor, MI 48104 (Pharmacy #5301008830), to the State of Michigan, Licensing and Regulatory Affairs (LARA), for appropriate follow-up regarding the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection.

FDA inspected the firm from January 12, 2016, to January 29, 2016. The Michigan State Board of Pharmacy was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found in Attachment 1.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Clark Professional Pharmacy, LLC, 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. Specifically, the firm failed to use sterile wipes as part of the disinfection program for the aseptic processing area.

In addition, the firm's program to ensure that each process performed 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, media fills are not performed under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

Clark Professional Pharmacy, LLC, committed to FDA in its response to the Form FDA 483, received February 11, 2016, to correct the deviations in the Form FDA 483. A copy of the firm's response to the Form FDA 483 can be found in Attachment 2. 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, 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 State of Michigan, Licensing and Regulatory Affairs (LARA) 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 Cicely Vaughn, Compliance Officer, at 313-393-8297, or by email at cicely.vaughn@fda.hhs.gov.

Sincerely,

Art O. Czabaniuk
District Director
Detroit District Office