U.S. Food and Drug Administration
Division of Pharmaceutical Quality
Operations I
New Jersey District
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June 8, 2017

Caroline D. Juran, RPh, DPh
Executive Director
Virginia State Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Dear Ms. Juran :

The purpose of this letter is to refer to the Virginia 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 Virginia BOP, Akina Pharmacy, located at 4080 Lafayette Center Drive Suite 270, Chantilly, VA 20151 (Pharmacy license number #0201004538).

FDA inspected the firm from July 25, 2016 to August 10, 2016. The Virginia BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A redacted copy of a Form FDA 483 that documents our investigator observations from the inspection can be found at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm520162.pdf

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Akina Pharmacy 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 distributes. In the response to the Form FDA 483, dated August 24, 2016, the firm advised FDA that "all medications dispensed from Akina to patients are patient specific and are always pursuant to a valid prescription from a physician."

During the inspection, the FDA investigator 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 did not have established contact times for the use of their sporicidal and disinfectant agents in order to achieve adequate cleaning and disinfection of work surfaces, supplies, and equipment within the aseptic processing areas.

2. The investigator observed the firm did not follow their depyrogenation procedure, and therefore it was unclear whether the equipment and supplies used in the production of products intended to be sterile were depyrogenated prior to use.

Akina Pharmacy committed to FDA in its response to the Form FDA 483, dated August 24, 2016, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. 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, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Virginia 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 Ernest Bizjak, Compliance Officer, at 301 796-4081, or by email at Ernest.Bizjak@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
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Diana Amador-Toro
District Director
New Jersey District