U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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VIA PARCEL COURIER

January 29, 2020

Caroline D. Juran
Executive Director
Virginia State Board of Pharmacy
Perimeter Center
9960 Maryland Drive, Suite 300
Henrico, Virginia, 23233-1463

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, AcariaHealth Pharmacy, Inc., located at 2924 Telestar Court, Falls Church, VA 22042-1206 (Pharmacy License# 0201004179).

FDA inspected the firm from August 27, 2018, to September 12, 2018. The Virginia State BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/123136/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by AcariaHealth 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.

Additionally, 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 at risk. Examples of deviations observed during our inspection include:

1. Non-microbial contamination was observed in your production area.
2. The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.
3. You used a non-pharmaceutical grade component in the formulation of a drug product.

AcariaHealth Pharmacy committed to FDA in its responses to the Form FDA 483, received September 27, 2018, 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. Furthermore, the firm stated in a letter to FDA dated October 17, 2019, that they have chosen to discontinue compounding operations at this location on or around April 30, 2019.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Virginia 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 send your electronic inquiries to orapharm1_responses@fda.hhs.gov.

You may also contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or call 1-518-453-2314 X-1014.

Craig W. Swanson -S

Digitally signed by Craig W. Swanson -S
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For Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I / New Jersey District