U.S. FOOD & DRUG ADMINISTRATION

Aziz I. Shaibani, M.D., F.A.C.P., F.A.A.N., F.A.N.A.
Clinical Professor of Medicine
Baylor College of Medicine
St. Luke's Medical Tower
6624 Fannin #1670
Houston, TX 77030

Dear Dr. Shaibani:

This letter informs you of the findings of a U.S. Food and Drug Administration (FDA) inspection conducted at your site between February 24, 2020, and February 28, 2020. Investigator Anya D. Lockett-Evans, representing the FDA, reviewed your conduct of a clinical investigation (Protocol **E05-CL-3004 (STEP)**, "A Phase III, Double-blind, Randomized, Placebo-controlled, Multicenter Study Evaluating the Efficacy and Safety of Qutenza® in Subjects with Painful Diabetic Peripheral Neuropathy") of the investigational drug Qutenza® (capsaicin), performed for Averitas Pharma, Inc.

This inspection was conducted as a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of the human subjects have been protected.

We have reviewed the FDA Establishment Inspection Report and the documents submitted with that report, and we did not identify any objectionable conditions or practices that would justify enforcement action by the Office of Compliance.

No response to this letter is necessary. However, if you have any questions or concerns about this letter or the inspection, please write to me at the address given below.

Sincerely,

{See appended electronic signature page}

Kassa Ayalew, M.D., M.P.H.
Branch Chief
Good Clinical Practice Assessment Branch
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Office of Scientific Investigations
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/s/

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06/19/2020 09:23:47 AM
Signed for Kassa Ayalew, M.D., M.P.H.