WARNING LETTER

Date: August 19, 2020

TO: <u>info@living-senior.com</u> – Justin Hartfield

Living Senior, LLC 2780 S. Jones Blvd

#200-3928

Las Vegas, NV 89146

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your websites at the Internet addresses www.blueribbonhemp.com and www.blueribbonhemp.com offers CBD products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of H TJ EMC /Lx cs 0 scn 6.48 -0 0 6.48 50.4 78.6 Tm (3)Tj 9.

Some examples of the claims on your websites that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- x "Dr. Bob Melamede discusses how NAC and CBD Fight Viral Infections like Coronavirus. . . Dr Bob also has a Web site called CBDSeniors.com, where you can find some of his work and what he does there, talking about mainstream CBD being available for the seniors and what pivotal role hemp and cannabis and CBD in all these goodies help as we're aging. We want these preventatives in in [sic] disease." [from your website <a href="www.blueribbonhemp.com/blog/dr-bob-melamede-discusses-how-nac-and-cbd-fight-viral-infections-like-coronavirus/#]
- x "The attached article shows how high doses of NAC can have extremely beneficial effects on a population of people suffering influenza infection. Influenza kills using the same mechanism as does COV-19, excess free radical production induced ARDS (Adult Respiratory Distress Syndrome)." [www.cbdseniors.com/study-attenuation-of-influenza-like-symptoms-with-nac-nacetylcysteine-supplements/]
- x "Dr. Bob's Approach to Life & the Coronavirus COVID-19 . . . You can save many lives by understanding what I present to you. . . Corona infection disrupts free radical homeostasis. Fat burning, is an adaptive energy source for reducing excess free radicals, may aid viral development . . . NAC (n-acetyl cysteine) Is very neuro-protective. It recharges the major antioxidant glutathione and therefore will reduce excess free radical production to minimize cell death. CBD blocks CB1 and stimulates CB2 receptors which turn on fat burning." [from your website www.cbdseniors.com/dr-bobs-approach-to-life-the-coronavirus-covid-19/]
- x "HOW TO DEAL WITH THE CORONAVIRUS [emphasis in original] WITH RICHAP]TJ 0 Tc-9.6 (CHA)-1 (P9

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the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.