WARNING LETTER

Date: November 30, 2020

TO: sales@avazo.com

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web@cbdmarketweb.com

CBD Market Web
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info@covidtests.shop

COVID Test Shop
605 Louis Dr Ste 502
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RE: Adulterated, 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) reviewed your websites at the Internet addresses https://www.covidtests.shop and www.cbdmarketweb.com on August 21, 2020 through November 16, 2020. We have also reviewed your social media websites at https://www.facebook.com/avazodetensor/, https://www.facebook.com/cbdmarketweb/, and https://www.instagram.com/cbdmarketweb/, where you direct consumers to your websites https://www.covidtests.shop and www.cbdmarketweb.com to purchase your products. The FDA has observed that your websites offers COVID-19[1] test kit products and CBD products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.

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 HHS.[2] In addition, on March 13, 2020, the President

[1] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

[2] Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx). The declaration has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 23, 2020. (Accessible at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx).

declared a national emergency in response to COVID-19.[3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

COVID-19 Test Kit Products

The FDA has observed that your website, www.covidtests.shop, offers two COVID-19 antigen test kit products for sale: "COVID-19 Ag Rapid Test Cassette (Box of 25) for Qualitative Detection of SARS-CoV-2 Antigen in Swabs. CE." and "COVID-19 Coronavirus Spike Glycoprotein Antigen Ag Rapid Test Kit by Sputum or Stool. CE. Box of 25." (collectively, "COVID-19 antigen tests"). Based on our review, these products are intended for use in the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 in people, and thus, are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h).

The COVID-19 antigen tests are offered for sale and distributed in the United States without marketing approval, clearance, or authorization from FDA. Accordingly, these products are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). These products are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. § 331(a). In addition, it is a prohibited act under section 301(k) of the Act, 21 U.S.C. § 331(k), to do any act with respect to a device while the device is held for sale after shipment in interstate commerce and results in the device being misbranded.

During our review, we also noted that your website, www.covidtests.shop, offers serology test kit products for sale, including the "COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). FDA EUA. Box of 25,"[4] and the "FDA EUA CE Approved Coronavirus (COVID-19) IgM/IgG Rapid Test Kit by Assure Tech. Box of 20."[5] The EUAs authorizing the emergency use of the Healgen Rapid Test Cassette and the Assure Rapid Test Device limit the distribution and use of those products to "authorized laboratories" – they do not authorize the sale of those products directly to consumers. Please address in your response to this letter the measures your firm has put in place to ensure that the Healgen Rapid

[3] President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

[4] The "COVID-19 IgG/IgM Rapid Test Cassette" offered for sale on your website appears to be the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) manufactured by Healgen Scientific LLC ("Healgen Rapid Test Cassette"). On May 29, 2020, FDA issued an Emergency Use Authorization (EUA), pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of the Healgen Rapid Test Cassette by "authorized laboratories" which is defined in the EUA as laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests.

[5] The "Coronavirus (COVID-19) IgM/IgG Rapid Test Kit" offered for sale on your website appears to be the Assure COVID-19 IgG/IgM Rapid Test Device manufactured by Assure Tech. (Hangzhou) co., Ltd. ("Assure Rapid Test Device"). On September 23, 2020, FDA issued an EUA, pursuant to section 564 of the Act, 21 U.S.C. § 360bbb-3, to permit emergency use of the Assure Rapid Test Device by "authorized laboratories" which is defined in the EUA as laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests and patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Test Cassette and the Assure Rapid Test Device are sold only to "authorized laboratories" in accordance with the provisions of their respective EUAs.

For more information about FDA's regulation of devices used to mitigate, prevent, treat, diagnose, or cure COVID-19; frequently asked questions; and other helpful resources, visit our website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-pandemic. In addition, the guidance titled "Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)"[6] provides information about FDA's policies intended to help expand testing capacity by facilitating the development and use of COVID-19 tests during the public health emergency.

Please direct any inquiries to FDA regarding your COVID-19 test kit products to: COVID-19-Task-Force-CDRH@fda.hhs.gov.

CBD Products

The FDA has observed that your website www.cbdmarketweb.com offers CBD products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.[7] 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).

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:

- On a page titled, "Two Points of View on CBD for Coronavirus Therapy" your website states
  - "COVID-19 AND CANNABIS? . . . Israeli researchers will utilize antiviral agents found in cannabis terpenes to slow the spread of the novel coronavirus. . . . Other Israeli scientists have begun research into what role CBD could play in COVID-19 treatment. While Meiri and his team will explore terpenes as antiviral agents, the clinical trial will utilize CBD's anti-inflammatory properties to reduce symptoms and regulate the body's immune system." [from your website https://www.cbdmarketweb.com/cbd-coronavirus-therapy/]

- You caption a link with the tags "#covid19cbd" and "#cbdcoronavirus." The link description states "CBD Products Online Store" and links to your website's page titled, "Two Points of View on CBD for Coronavirus Therapy" [from a May 14, 2020 post on your Facebook social media website, https://www.facebook.com/cbdmarketweb/]

Please direct any inquiries to FDA regarding your CBD products to: COVID-19-Task-Force-CDER@fda.hhs.gov.

You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and/or effective for

[6] Accessible at https://www.fda.gov/media/135659/download.
[7] The FTC reviewed your website www.cbdmarketwatch.com and your Facebook social media website, https://www.facebook.com/cbdmarketweb/ on November 19, 2020.

a COVID-19-related use for which they have not been approved, cleared, or authorized by FDA and that you do not make claims that adulterate or misbrand the products in violation of the Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDRH@fda.hhs.gov** and **COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and are being misleadingly represented as safe and/or effective for the mitigation, prevention, treatment, diagnosis, or cure 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 Act. This list can be found at https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products. Once you have taken corrective actions to cease the sale of your unapproved, uncleared, and unauthorized product(s) 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 product is not in violation of the Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be adulterated or misbranded are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products listed above to be adulterated and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDRH@fda.hhs.gov and COVID-19-Task-Force-CDER@fda.hhs.gov.

In addition, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Timothy T. Stenzel -S

Timothy Stenzel, M.D., Ph.D.
Director
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Donald D. Ashley -S

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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

SERENA VISWANATHAN

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Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission