



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

Date: October 30, 2020

TO: bob@watershed.net – Robert McCauley
info@watershed.net Spartan Enterprises & Technology, Inc.
dba Watershed Wellness Center
16280 National Parkway
Lansing, MI 48906

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 website at the internet address <https://watershed.net> on October 7, 2020, and October 28, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/WatershedWellness> and <https://www.youtube.com/user/watershed11>, where you direct consumers to your website at <https://watershed.net> to purchase your products. The FDA has observed that your website offers “Dissolve BioActive Silicate,” and products labeled to contain silver, 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 HHS.² In addition, on March 13, 2020, the President 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

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 twice. The most recent renewal went into effect on July 25, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. July 23, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx>).

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/>).

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.

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:

- Below the header “Silver Kills Viruses” you represent, “Today, Planes are arriving from China carrying one of the most deadly viruses every known, the Coronavirus. The best way to protect yourself against this is with liquid angstrom silver.” (*sic*) [from your website at <https://blog.watershed.net/2020/02/10/silver-kills-viruses/>]
- In a video entitled “Does Silver Cure C@vid19,” a banner on the screen reads “Silver kills all viruses including COVID19” and you represent, “Now let's talk about the virus that's running all over the world and, and wreaking havoc, and keeping everybody in their homes. Will silver, this kind of silver, kill that virus? Well yes! Silver will kill that virus. It will kill any virus, any bacteria, yeast, mold, and fungus, nothing can survive it. So, this means when you take this, the virus will be killed, well it might kill some of it.” (*sic*) [from an April 7, 2020 YouTube video at <https://www.youtube.com/watch?v=7IWg8HVk5No>]
- In a video entitled “What Would Dr. Bob Do If He Got a Virus,” you represent, “Hi folks, everybody's asking what to do about this coronavirus. Well I'm going to tell you how I cured myself of meningitis, back in 2012 with just taking two caps of silver, just like that liquid angstrom silver, uh I thought I didn't know I was sick I thought I was been poisoned or something I went on for about ten days and then I took a trip to China and it just came back like that. That's a killer. Meningitis is a killer. It's nothing compared to this thing this is not anywhere near something as serious as meningitis that attacks your entire nervous system.” (*sic*) [from a March 28, 2020 YouTube video at <https://www.youtube.com/watch?v=bQ3bXerqCy8>]
- In a video entitled “Dissolve BioActive Silicate Kills Viruses Removes BIOFILM,” you represent, “Hi folks, Dr. Bob McCauley. More suggestions on what to do about that coronavirus that's out there. Another product I recommend for the any kind of virus, any kind of bacteria, just because you want to clear out the digestive tract as much as possible, get the arteries cleared, make sure it's healthy as possible, and you want to get yourself in an, you know, in an environment where your body is not full of bacteria, not full of yeast, not full of viruses, mold, fungus, this kind of stuff. You really want all these infectious agents out of there, and one of my best product 'course is Dissolve BioActive Silicate.” (*sic*) [from a March 18, 2020 YouTube video at <https://www.youtube.com/watch?v=5LYQ-WD1IQM> and attached to a March 18, 2020 post on your Facebook page at <https://www.facebook.com/WatershedWellness>]
- In a video entitled “Liquid Angstrom SILVER For VIRUSES of Every Kind,” you represent, “Hi folks, Dr. Bob McCauley, with this coronavirus going around and everything, a lot of people ask me what, what are you doing for, well I'm gonna do a quick series of videos to show you what I would do if I got the coronavirus, what I would do to prevent coronavirus, and uh you know how I cured myself a meningitis. Meningitis is a lot more dangerous and a lot more deadly than the coronavirus and this is how I did it. Your biggest weapon uh in fighting any kind of infectious disease is silver. Liquid angstrom silver is the best kind of silver in my opinion I don't think anything else comes close.” (*sic*) The video description contains the hashtags “#silver #coronavirus #coronavirusoutbreak #coronaviruses #virus #antibiotics.” [from a March 14, 2020 YouTube video at

<https://www.youtube.com/watch?v=MqxSFHjcWXU> and attached to a March 15, 2020 post on your Facebook page at <https://www.facebook.com/WatershedWellness>]

- In a video entitled “Silver KILLS Viruses,” you represent, “Hi folks, Dr. Bob McCauley, what do you do when a virus epidemic strikes? This is what you do. Well we've heard in the news lately that there is a virus epidemic and they've never seen a virus like this, who knows how it got started, who knows where, you know, how it really got going. It doesn't matter. It looks like it's going to be spreading all over the planet and that's a very serious thing. So what would I do if I was struck by this or I got into a situation where I knew I was around contaminated people, this is what I would do. I would stop eating immediately and I would start taking this liquid angstrom silver.” (sic) [from a February 11, 2020 YouTube video at <https://www.youtube.com/watch?v=ErLP2vMpLaU>, attached to a February 11, 2020 post on your Facebook page at <https://www.facebook.com/WatershedWellness>, and embedded on your website at <https://watershed.net>]

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 FD&C Act and FDA's 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 effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to 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 that are being misleadingly represented as safe and/or effective for 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.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs 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 product(s) referenced above to be unapproved 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-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,

Sincerely,

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

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