



## **WARNING LETTER**

Date: March 1, 2021

TO: [agelesslabs@gmail.com](mailto:agelesslabs@gmail.com) Ageless Global, LLC  
2722 S. West Temple  
Salt Lake City, UT 84115

CC: agelessgloballab.com: [agelessgloballabcom@domainsbyproxy.com](mailto:agelessgloballabcom@domainsbyproxy.com)  
cvk365.com: [cvk365.com@domainsbyproxy.com](mailto:cvk365.com@domainsbyproxy.com)  
covid19mdhub.com: [covid19mdhub.com@domainsbyproxy.com](mailto:covid19mdhub.com@domainsbyproxy.com)  
lionsfuel.com: [lionsfuel.com@domainsbyproxy.com](mailto:lionsfuel.com@domainsbyproxy.com)  
mdimmunespray.com: [mdimmunespray.com@domainsbyproxy.com](mailto:mdimmunespray.com@domainsbyproxy.com)  
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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 [www.agelessgloballab.com](http://www.agelessgloballab.com), [www.cvk365.com](http://www.cvk365.com) (which redirects to [www.agelessgloballab.com](http://www.agelessgloballab.com)), [www.covid19mdhub.com](http://www.covid19mdhub.com), [www.lionsfuel.com](http://www.lionsfuel.com), [www.mdimmunespray.com](http://www.mdimmunespray.com), [www.mdmouthspray.com](http://www.mdmouthspray.com) on January 19, 2021 and January 18, 2021, respectively. In addition, we have reviewed your social media websites <https://www.instagram.com/immunoralcvk365>, [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/), <https://www.facebook.com/Ageless-Global-101773438401247>, [https://twitter.com/Ageless\\_Global/](https://twitter.com/Ageless_Global/), and <https://www.linkedin.com/company/ageless-global/> where consumers are directed to your websites to purchase your products. The FDA has observed that your websites offer the products “Immunoral,” “Immune Plus,” “MD Immune Support Spray,” and “MD CVK-365 Mouth Spray” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> 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.<sup>2</sup> In addition, on March 13, 2020, there was a

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<sup>1</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>2</sup> Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed) *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

Presidential declaration of a national emergency in response to COVID-19.<sup>3</sup> 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 any 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:

- “Immunoral is a therapeutic combination of CBD, nano-silver, specialized mineral oxide NSF-60 water, and Vitamin C that show promise to naturally defend against the current SARS-CoV-2 pathogen, the cause of COVID-19 in the body.” [From your webpage <https://www.agelessgloballab.com/immunoral>].
- “Immunoral Can Help You Protect Your Body Against COVID-19 By Supporting Your Natural Immune System . . . Immunoral Gives You Peace Of Mind, Protection, and Reassurance that You are Doing What is Possible to Defend Against COVID-19 . . . Immunoral Can Keep Your Body Stronger and Healthier to Defend against COVID-19 . . . Immunoral Effortlessly Helps Support Your Bodies [sic] Ability To Fight Off, Viruses Like COVID-19” [From your webpage <https://www.agelessgloballab.com/immunoral>].
- “The Company’s portfolio of technology and products currently include two patent-pending, clinically tested COVID-19 defense products.” Referring to your MD CVK-365 Mouth Spray and Immunoral CVK-365 products. [From your website, [www.agelessgloballab.com](http://www.agelessgloballab.com)].
- “Immunoral CVK-365 . . . Immune-based Therapy for COVID-19 Defense . . . Immunoral Mouth Spray, an immune-based adjunct therapy combination of CBD, nano-silver and NSF 60 mineral oxide water (CVK-365) and Vitamin C that shows promise to naturally defend against the current SARS-CoV-2, the virus that causes COVID-19 in the body. This therapy is grounded in the science pertaining to the immune system with proven ingredients that work synergistically. An initial test group that has been taking Immunoral since March 2020 resulted in great success where not one participant has contracted COVID-19.” [From your website, [www.agelessgloballab.com](http://www.agelessgloballab.com)].
- “I Have Had Great Success Helping People Bounce Back Fast From COVID-19 With Two Specific Products That Have Been Tested On The COVID-19 Pathogen . . . The ability to naturally start attacking the COVID-19 as soon as you find out you have it.” Referring to your Immunoral CVK-365 product. [From your website, [www.covid19mdhub.com](http://www.covid19mdhub.com)].
- “Tested and affordable, Immune Plus Mouth Spray supports natural immune defense to inactivate, attack and shield against foreign pathogens like COVID-19, to safeguard your health.” [From your website, [www.lionsfuel.com](http://www.lionsfuel.com)].
- “Take three minutes and learn Four Simple Things that Could Help Protect You from Viruses (Corona, Sars, Bird and others) . . . DON’T LIVE IN FEAR OF THE CORONA VIRUS . . . Weak immune systems make an easy target for viruses. Take action to start strengthening your

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<sup>3</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

immune system today.” Referring to your MD IMMUNE SUPPORT SPRAY product. [From your website, [www.mdimmunespray.com](http://www.mdimmunespray.com)].

- “MD CVK-365 Mouth Spray contains clinically proven CVK-365 water and other natural ingredients to help you naturally defend against pathogens including COVID-19 . . . Tested and affordable, MD CVK-365 Mouth Spray supports natural immune defense to inactivate, attack and shield against foreign pathogens like COVID-19, to safeguard your health . . . MD CVK-365 Mouth Spray Dual Action defense has been clinically tested by an Independent Research Lab (Clinical USA) on hard surfaces and is shown to inactivate the SARS-CoV-2 virus at over 98% within 2-minutes with no regrowth in 48-hours.” [From your website, [www.mdmouthspray.com](http://www.mdmouthspray.com)].
- “‘With the vaccine being in question for kids 17 and younger, MD CVK-365 Mouth Spray is a viable option of added defense,’ said Ageless Global Medical Director, Dr. Steven E. Warren.” The post includes an image with your website address “AGELESSGLOBALLAB.COM” [From December 28, 2020 posts on your social media websites [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/) and <https://www.facebook.com/Ageless-Global-101773438401247>].
- “Still looking for a last-minute Christmas gift? Give your loved ones the gift of protection against SARS-CoV-2, bacteria, and other viruses for the holidays with Immunoral.” The post includes an image with your website address “AGELESSGLOBALLAB.COM.” [From December 18, 2020 posts on your social media websites [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/) and <https://www.facebook.com/Ageless-Global-101773438401247>].
- “An initial test group has been taking Immunoral since Mar. 2020 with great success not contracting COVID-19. It is a combination of CBD, nano-silver, NSF-60 water, and Vitamin C, showing promise to naturally defend against the pathogen.” The post includes an image with your website address “AGELESSGLOBALLAB.COM.” [From a December 14, 2020 post on your social media website [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/)].
- “Help us create a solution to the pandemic. Available in raspberry lime flavors, Immunoral CVK-365 is an immune-based therapy for COVID-19 defense. Get 50% when you sign up to be a participant in our IRB research study.” The post includes your website address [cvk365.com](http://cvk365.com). [From December 9, 2020 posts on your social media websites [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/) and <https://www.facebook.com/Ageless-Global-101773438401247>].
- “How to use Immunoral? Spray it in your mouth five times in the morning and again five times at night. It will help you to naturally defend against the current SARS-CoV-2 pathogen, the cause of COVID-19 in the body. . . . [L]earn how you could join our immune defense study today.” [From November 2, 2020 posts on your social media websites [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/) and <https://www.facebook.com/Ageless-Global-101773438401247>].
- “Ageless Global, LLC . . . a leading developer and supplier of physician-backed, clinically-tested wellness products to better equip our nation with the defense needed to combat COVID-19, announced today the launch of . . . Immunoral Oral Spray. . . an immune-based adjunct therapy combination of CBD, nano-silver, NSF 60 mineral oxide water (CVK-365) and Vitamin C that shows promise to naturally defend against SARS-CoV-2, the virus that causes COVID-19 in the body.” [From a press release titled, “Ageless Global Launches Clinically-Tested COVID-19 Defense Therapies and Products in Response to Pandemic” dated October 27, 2020, and accessible at <https://www.accesswire.com/612357/Ageless-Global-Launches-Clinically-Tested->

[COVID-19-Defense-Therapies-and-Products-in-Response-to-Pandemic](#), linked from your website at [www.agelessgloballab.com/recent-news](http://www.agelessgloballab.com/recent-news)].

- “Immunoral: a new immune-based therapy against the COVID-19 pathogen” accompanied by an image of Immunoral and the text “WWW.CVK365.COM.” [From a December 30, 2020 post on your social media website <https://www.instagram.com/immunoralcvk365>].
- “Immunoral CVK-365 . . . helps you naturally defend against the current SARS-CoV-2 pathogen . . . CVK365.COM” [From a December 22, 2020 post on your social media website <https://www.instagram.com/immunoralcvk365>].
- “Aiming to boost your #fitness during quarantine? Lion’s Fuel Immune Plus is a new mouth spray that supports natural #immune defense to shield against pathogens, like #COVID19” [From a January 19, 2021 tweet from your social media website [https://twitter.com/Ageless\\_Global/status/1351629238961463298](https://twitter.com/Ageless_Global/status/1351629238961463298)].

In addition, your Immunoral product is also misbranded under section 502 of the FD&C Act, 21 U.S.C. § 352, because your firm’s website, product label and/or social media pages falsely suggest that the “Department of Health and Human Services (HHS) approved as an IRB study” using Immunoral. However, we note that the HHS does not approve studies and that the registration for the IRB that you list “IORG001078,” expired on April 14, 2014. For example, you state:

- “What precautions are you taking to protect yourself against COVID-19? We have developed a patent-pending, adjunct therapy, Immunoral oral spray that the Department of Health and Human Services approved as an IRB study. Learn more about the study: [www.cvk365.com](http://www.cvk365.com)” [From a November 16, 2020 post on your social media website [https://www.instagram.com/ageless\\_global/](https://www.instagram.com/ageless_global/)].
- “Join the Immunoral mouth spray COVID-19 Immune Defense Study! Department of Health and Human Services has approved the Immunoral IRB #(IORG001078) For more information about the Immunoral IRB click the link in the bio!” [From an October 7, 2020 post on your social media website <https://www.instagram.com/immunoralcvk365/>].
- “Join our IRB study for Immunoral. This research will focus on a specialty adjunct therapeutic, which is proven effective in boosting the immune system, increasing the potential to naturally defend itself against the effects of the virus. <https://cvk365.com/> . . . #COVID19” [From your LinkedIn website <https://www.linkedin.com/company/ageless-global/>].
- The label of your Immunoral product states “Available Only Through IRB Registration at [www.CVK365.com](http://www.CVK365.com).”

You should take immediate action to address 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](mailto:COVID-19-Task-Force-CDER@fda.hhs.gov)** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately any violations 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 actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. 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 may be detained or refused 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](mailto: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. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to \$43,792 per violation. 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](mailto: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,

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

Sincerely,

Serena Viswanathan  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission