



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



## **WARNING LETTER**

Date: April 9, 2020

TO: [dpo@freespeechsystems.com](mailto:dpo@freespeechsystems.com) – Mr. Alexander E. Jones, Free Speech  
Systems LLC  
d.b.a. Infowars.com  
3005 S Lamar Blvd  
Ste D109-398  
Austin, TX 78760-9549

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.infowarsstore.com](http://www.infowarsstore.com) on March 26, 2020 and April 6, 2020, respectively. We also reviewed your websites at the Internet addresses [www.infowars.com](http://www.infowars.com) and [www.banned.video](http://www.banned.video), where you direct consumers to your website, [www.infowarsstore.com](http://www.infowarsstore.com), to purchase your products. The FDA has determined that your [www.infowarsstore.com](http://www.infowarsstore.com) website offers “Superblue Silver Immune Gargle,” “SuperSilver Whitening Toothpaste,” “SuperSilver Wound Dressing Gel” and “Superblue Fluoride Free Toothpaste” 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, the President declared a national emergency in response to COVID-19.<sup>3</sup> Therefore, FDA is taking urgent measures to protect consumers from certain

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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 Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

<sup>3</sup> 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/>).

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.

Some examples of the claims on videos posted 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:

- A video posted on 3/10/2020, titled “Alex Jones Deep States: Using Coronavirus Fear and Panic To Destroy Our Country.” At minute 13:25, you state: “[R]egardless of how deadly this virus is . . . if it kills you, it's bad news. So, I would advise listeners, just for your everyday life anyway to boost your immune system. We have the products that are documented on record to be good for your body. I mean Nano Silver is on record taking out viruses and bacteria. It's in our entire line of high quality silver products and it's patented, it's amazing, it's in the Super Silver Wound gel, it's in the Super Silver Toothpaste, it is in the Super Blue Toothpaste . . . we're very close to selling out in infowarsstore.com . . . ” [from your website <https://banned.video/watch?id=5e675a2412f790009b69bfa4>, Last accessed on 3/26/20]
- A video posted on 3/10/2020, titled “Experts Say Trump Must Seal The Border Like Israel & Italy Or Face Massive Coronavirus Surge.” At minute 31:08, you state “I'm not going to belabor this, I'm just gonna tell ya, that for just your daily life, and your gums and your teeth and for regular viruses and bacteria, the patented Nano Silver we have, the Pentagon has come out and documented, and homeland security have said this stuff kills the whole SARS corona family, at point blank range. Well of course it does, it kills every virus. But they found that, this is 13 years ago, and the Pentagon uses the product we have. And the product we have in private label is about to be in Walmart . . . the Nano Silver toothpaste in the Superblue with the tea tree and the iodine, that's the Superblue's amazing, and we have the whitening toothpaste that has the Nano Silver and a lot more as well . . .they are at infowarsstore.com” [from your website <https://banned.video/watch?id=5e6819988247dc001606b884>, Last accessed on 3/26/20]
- A YouTube video embedded on your website that was posted on 2/9/2020, titled “Coronavirus – Is This The Virus that DIDN'T Cry Wolf?” At minute 2:30, “we're independently sponsored by InfoWars” and at minute 3:50, “If you are concerned about the Coronavirus or the Flu or the common cold, then I recommend you to go to the Infowars store, pick up a little bit of silver that really acts its way to boost your immune system and fight off infection . . .” At minute 3:58, the video shows your Superblue Silver Immune Gargle product. [from your website <https://infowars.com/coronavirus-is-this-the-virus-that-didn-t-cry-wolf/>, Last accessed on 3/26/20]

You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are 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 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](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 products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products 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 [COVID-19-Task-Force@ftc.gov](mailto:COVID-19-Task-Force@ftc.gov).

Sincerely,

U.S. Food and Drug Administration

Sincerely,

Federal Trade Commission