



## **WARNING LETTER**

Date: October 23, 2020

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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 <a href="www.covercology.com">www.covercology.com</a> on September 8, 2020 and September 30, 2020, respectively. We also reviewed your social media website at <a href="www.facebook.com/Hairreau">www.facebook.com/Hairreau</a>, where you direct consumers to your website, <a href="www.covercology.com">www.covercology.com</a>, to purchase your products. The FDA has observed that your website offers the product "Simple Silver" for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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 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 a product that is 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 your websites that establish the intended use of your product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx).

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<sup>&</sup>lt;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>&</sup>lt;sup>2</sup> Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <a href="https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx">https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx</a>). 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

- "Simple Silver (Colloidal Silver) with ionic solubility technology is a dietary supplement that has ionic solubility that may supports the Immune system ability to fight off and kill nasty pathogens that can cause illnesses inside and outside the body such as: CORONAVIRUS (COVID-19) . . . Ideal for dedicated health care professionals working with Covid-19 patients . . ." [from your website www.covercology.com/shop]
- "Human coronaviruses can sometimes cause lower-respiratory tract illnesses such as pneumonia or bronchitis. Simple Silver is a dietary supplement that has ionic solubility that supports the Immune system in it's ability to fight off and kill nasty pathogens that can cause illnesses inside and outside the body such as: CORONAVIRUS (COVID-19) . . . Try it today! . . . link in bio" [from a February 28, 2020 post on your social media website <a href="https://www.facebook.com/Hairreau">www.facebook.com/Hairreau</a>]

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-CFSAN@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 uS0001 Tna1 TEMC /, telated uroducts yn violation of the FD&C Act. os lest oan sbl5.3 (afoud ant ]TJEMC /Link &MCID 139BDC /CS0 cs 0.