

WARNING LETTER

Date: March 26, 2020

TO: info@carahealth.ie – Carina Harkin
info@carahealth.com Carahealth
24 Waterlane, Galway, Ireland

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.carahealth.com in March 2020. We also reviewed your social media website at www.facebook.com/pg/herbaltonics, where you direct consumers to your website at www.carahealth.com to purchase your products. The FDA has determined that your website offers herbal products, including “Carahealth Immune,” which is also referred to as “Immune Tonic” on your website, for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. FDA has determined that these products are unapproved new drugs ~~that are not intended to diagnose, cure, mitigate, prevent, or treat COVID-19~~ and are ~~not~~ ~~intended~~ ~~to~~ ~~diagnose,~~ ~~cure,~~ ~~mitigate,~~ ~~prevent,~~ ~~or~~ ~~treat~~ ~~COVID-19~~ (COVID-19) in people. FDA has determined that these products are unapproved new drugs ~~that are not intended to diagnose, cure, mitigate, prevent, or treat COVID-19~~ and are ~~not~~ ~~intended~~ ~~to~~ ~~diagnose,~~ ~~cure,~~ ~~mitigate,~~ ~~prevent,~~ ~~or~~ ~~treat~~ ~~COVID-19~~ (COVID-19) in people. FDA has determined that these products are unapproved new drugs ~~that are not intended to diagnose, cure, mitigate, prevent, or treat COVID-19~~ and are ~~not~~ ~~intended~~ ~~to~~ ~~diagnose,~~ ~~cure,~~ ~~mitigate,~~ ~~prevent,~~ ~~or~~ ~~treat~~ ~~COVID-19~~ (COVID-19) in people.

² 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>).

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/>).

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:

- x “Coronavirus (COVID-19, SARS-CoV-2) pandemic has no medical treatment. Natural antiviral herbs boost immunity & decrease virus virulence to achieve herd immunity.” [from your website at www.carahealth.com]
- x “Natural medicine to prepare for a global pandemic . . . Covid-19 is a corona virus like Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) and . . . Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV). Haemagglutinin exists in the structure of the coronavirus and is a target for herbal treatment. Neuraminidase inhibitors are the cornerstones of the management of patients hospitalised for suspected MERS-CoV infection and SARS corona virus hence neuraminidase is also a target for herbal treatment” [from your website at www.carahealth.com (citations omitted)]
- x “Carahealth Immune . . . Contains herbal medicines that have been shown to have the desired action in influenza, to inhibit ha[⁽ⁱ⁾541 6 (uenz) (nhi)2.6 (bi)6 (⁾5904 8i (bi)6ec)8.5 Tciunza, t vnhi

