WARNING LETTER

Date: April 21, 2020

TO: <u>info@coppertouch.com</u> – Linda Pavek, Copper Touch, LLC

customerservice@coppertouch.com 6421 364th Street, North Branch, Minnesota 55056

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://coppertouch.com on April 15,1ì•À lz)8lÞ I

unapproved new drugs sold in violation of section 505(a) of the Fede (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are mixthe FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction interstate commerce is prohibited under sections 301(a) and (d) of th (d).

There is currently a global outbreak of respiratory disease caused by named "severe acute respiratory syndrome coronavirus 2" (SARS-Covirus has been named "Coronavirus Disease 2019" (COVID-19). On Health and Human Services (HHS) issued a declaration of a public hand 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 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 website that establishes 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 "Examples of Microbes Killed by our CopperTouch Products Include . . . Coronaviruses"
- x "Is copper effective against coronaviruses? . . . In a recent study by US health organizations, copper was shown to be more effective than any other surface tested at deactivating (killing) the HCoV-19 coronavirus."
- x "Because we do not have access to the actual HCoV-19 corona virus cells, based on the research reports and our knowledge of the manner in which copper kills germs (including bacteria and viruses), we do believe that CopperTouch will be effective in killing it."

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, 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-emergeti1sae [Tm [18 3D9ency Conlaring-

x "We believe there is adequate research

Sincerely,

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

Sincerely,

Richard A. Quaresima Acting Associate Director Division of Advertising Practices Federal Trade Commission