



WARNING LETTER

Date: July 10, 2020

TO: healn4u@healthbeautylove.com – Health Beauty Love
2212 Chickasaw Trail,
Orlando, FL 32825
United States

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://healthbeautylove.com/> on June 26, 2020, and July 7, 2020, respectively. We also reviewed your social media website at <https://www.instagram.com/healthbeauty.love/>, where you direct consumers to your website, <https://healthbeautylove.com/>, to purchase your product. The FDA has observed that your website offers a tincture 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. § 301(a) and mobilized the Operating Division to investigate the diagnosis, or cure of COVID-19.

Some examples of the claims on your websites that establish the existence of COVID-19 are as follows:

¹ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration was renewed for another 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.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/>).

- x A video embedded on your homepage, titled “E-Munity Promotional Video.” At minute 0:01, “INTRODUCING E-MUNITY OUR RESPONSE TO COVID-19.” At minute 0:07, “OUR HERBAL TINCTURE IS ANTI-VIRAL.” [from your website <https://healthbeautylove.com/>]
- x “Try Our Approach to COVID-19: E-Munity”
 - o “E-Munity is a

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.

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.