

WARNING LETTER

Date: April 6, 2020

TO: support@indigonaturals.net – Indigo Naturals

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://indigonaturals.net> on March 30, 2020 and April 2, 2020, respectively. We also reviewed your social media website at Internet address www.facebook.com/IndigoNaturals/, where you direct consumers to your website, <https://indigonaturals.net>, to purchase your products. The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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.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

with reduced microglial activation and pro-inflammatory cytokine production. . . .CBD will boost two of the T-cells powerful weapons (interferon and IL2) WHEN T cell function is LACKING. When T cell activity is too strong, it will actually suppress that activity . . . Levels of T cells in the lungs are important for the new coronaviruses” [from a February 12, 2020 blog posting on your website <https://indigonaturals.net>]

- x “Updated information on CBD (ACD2 receptors) and anti-viral effects in age of coronavirus: <https://indigonaturals.net/.../is-cbd-an-antiviral-agent-for> . . . Is CBD an Anti-Viral Agent for Coronavirus, Influenza, MERS, and Sars [sic] Plus Key Antiviral Supplements?” and the image of viruses with the words “CBD Anti VIRAL?” [from a February 26 post on your social media website

~~https://www.facebook.com/indigonaturals/~~

