



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: May 21, 2020

TO: info@apollohempire.com – Bryce Johnson, Apollo Holdings LLC
1670 Destiny Lane
Conway, SC 29526

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 websites at the Internet addresses, <https://apollohempire.com> and <https://www.noronapak.com>¹ on May 12, 2020, and May 18, 2020, respectively. We also reviewed your social media websites at <https://www.facebook.com/apollohempire/> and <https://twitter.com/ApolloHempire> where you direct consumers to your website, www.apollohempire.com, to purchase your products. The FDA has observed that your websites offer “NoronaPak” products, including cannabidiol (CBD) and other supplement products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19² 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.³ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁴ 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.

¹ The website, <https://www.noronapak.com>, directs consumers to <https://apollohempire.com> to purchase your products.

² As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

³ 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>). 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>).

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>).

⁴ 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:

- “What is COVID-19? Coronavirus is referred to as a novel cause for viral pneumonia because it’s a virus we haven’t seen before and have developed no immunity to. . . . What Happens If You Get Infected and What Can Help? . . . Regardless of the shape you’re in at this moment, there may be ways you can prepare and protect your body from developing a more severe response to infection. Explore the solutions included in NoronaPak below! [graphic with the following text] ‘Selenium, Cannabidiol (CBD), Vitamin-C, Zinc, Vitamin-D, N-Acetylcysteine’ . . . Supplementation with selenium results in changes in the gene expression that is required for protein biosynthesis in lymphocytes, the infection-fighting cells that are crucial to the immune system being able to identify infection and mount an immune response. . . . Selenium is not only important in boosting the immunity of the individual but also to slow the development of more virulent strains of some viral pathogens. . . . CBD may suppress the productions of cytokines in the setting of infection.” [from your website www.noronapak.com/about-noronapak]
- “Naturally derived supplements to Fortify your Immune system and battle symptoms of the flu! . . . FORTIFY YOUR BODIES [sic] DEFENSE AGAINST #covid19” [from an April 14, 2020 posting on your Twitter social media website <https://twitter.com/ApolloHempire/>]
- “Naturally derived supplements to Fortify your Immune system and battle symptoms of the flu! . . . FORTIFY YOUR BODIES [sic] DEFENSE AGAINST #covid 19 . . . #cbd #cbdmovement #cbdhealth #zinc #selenium #nacetylcysteine #vitamind #vitaminc . . . [graphic with the following text] ‘NORONAPAK IS DESIGNED TO PROVIDE YOU WITH A NATURALLY-SOURCED, PHARMACIST CURATED REGIMEN TO READY YOUR BODY AND BATTLE YOUR FLU-LIKE SYMPTOMS.’” [from an April 14, 2020 posting on your Facebook social media website <https://www.facebook.com/apollohempire/>]
- “Fight off Coronavirus with NoronaPak . . . Available now at apollohempire.com . . . The Norona Pak designed [sic] to provide you with a naturally-sourced, pharmacist curated regimen to ready your body and battle your flu-like symptoms. . . . [graphic with the following text] ‘1500 mg of Full Spectrum CBD Oil . . . 30 ct bottle of 25 mg Water Soluble CBD along with some Vitamins . . . 60 ct bottle of Effervescent Vitamin Tabs (Similar to Airborne or Emergen-C)’ . . . [graphic with the following text] ‘BOOST your Immune System . . . FORTIFY your bodies [sic] defense against viral Infections . . . SUPPRESS flu-like symptoms with Norona Pak’” [from a March 25, 2020 posting on your Facebook social media website <https://www.facebook.com/apollohempire/>]

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-CDER@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 the

treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at

<http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products>.

Once you have taken corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

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 products, 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. To make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

There currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure coronavirus disease 2019 (COVID-19). Thus, the claims cited above are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. In addition, you are advised to review all claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Sincerely,

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

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