



WARNING LETTER

Date: March 24, 2022

TO: mletefi@appliedbioinc.com

Mr. Michael Latefi
Applied Biological Laboratories
760 Parkside Ave., 317
Brooklyn, New York 11226

RE: Unapproved and Misbranded Product Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address <https://www.biovanta.com> and <http://www.appliedbioinc.com> in February and March 2022; the Federal Trade Commission (FTC) also reviewed these websites in March 2022. The FDA has observed that your website, <https://www.biovanta.com>, offers “Biovanta Dual Action Throat Spray” and “Biovanta Triple Action Lozenges” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. We also reviewed your social media websites at <https://twitter.com/appliedbiolabs> and <https://www.linkedin.com/company/appliedbioinc> where you direct consumers to your website, <https://www.appliedbioinc.com>, which directs consumers to <https://www.biovanta.com> to purchase your products. Based on our review, “Biovanta Dual Action Throat Spray” and “Biovanta Triple Action Lozenges” 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, there was a Presidential declaration of 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 a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

Some examples of the claims, including on your websites, that establish the intended use of your products and misleadingly represents them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “In conclusion, the scientific studies demonstrate that the active ingredients in Biovanta help reduce the inflammation that causes upper respiratory infections, including COVID-19, while leading brands, which are designed to mask symptoms, do more harm than good.” [from your webpage <https://biovanta.com/blogs/all/the-science-behind-biovanta-cold-cough-and-sore-throat-otc-medicine-scientifically-proven-safer-and-more-effective>]
- “Applied Biological Laboratories... launched Biovanta... Biovanta is proven superior to other leading products... in third-party, blind, placebo-controlled laboratory studies. The scientific publication titled ‘Rational drug design for sore throat – An aspirin-based treatment that addresses bradykinin-induced inflammation’ explains the studies in more detail. According to the publication, Biovanta modulates cytokines and strengthens the respiratory lining. Key inflammatory molecules studied include bradykinin, which is implicated in the cytokine storm associated with COVID-19 and other serious upper respiratory diseases... Applied Biological Laboratories Inc. is a New York-based biotechnology company committed to the research, development, and manufacturing of drugs and therapies for respiratory diseases such as rhinovirus, influenza, coronavirus (including COVID-19), adenovirus, others.” [from the December 3, 2020 article as provided by you to PRNewswire,⁴ <https://www.prnewswire.com/news-releases/biovanta--the-only-100-natural-safe-and-effective-over-the-counter-drug-for-cough-cold-and-sore-throat-301185288.html> and to which you directly link from your May 20, 2021 post entitled “Biovanta: The only 100% natural, safe and effective over-the-counter drug for cough, cold and sore throat” on your webpage <https://biovanta.com/blogs/all>]
- “Just published the first scientific paper to finally address what works for sore throat, also to prevent a #BradykininStorm, treat #COVID_19 #COVID19 #SARSCoV2 symptoms and prevent #AntibioticResistance.” This is followed by a link to an abstract of your firm’s study entitled “Rational drug design for sore throat – An aspirin-based treatment that addresses bradykinin-induced inflammation,” which mentions Biovanta. [from a November 8, 2020 post on your social media webpage <https://twitter.com/appliedbiolabs>]
- “Despite my best efforts of trying to avoid getting sick during this pandemic, three days ago I got diagnosed with COVID 19. I had all the symptoms. I had a fever, I had a sore throat. My friend recommended me this product when told them that I was quarantining. It’s called Biovanta. It’s all natural. I got it from my local CVS and it’s a two step spray. I immediately noticed that it just like cleared my airways and I could take a deep breath.” [from a video called “Biovanta really helped me feel better!” you posted on your www.amazon.com Biovanta Throat Spray product page]
- “More evidence that respiratory diseases should be treated in the nose and throat! <https://lnkd.in/drSQX38N> #biovanta #science #covid” [from a post on your social media webpage at <https://www.linkedin.com/company/appliedbioinc>]
- “Study shows use of low-dose aspirin may prevent and shorten the duration of COVID-19 infection. More reasons to love our active ingredient. #science #covid—19 #innovation #health #aspirin #biovanta <https://lnkd.in/eu3bm23K>” [from a post on your social media webpage at <https://www.linkedin.com/company/appliedbioinc>]

⁴ According to the Cision PRNewswire Client Terms & Conditions a “Client” purchases services from Cision and/or its affiliates and “[f]or each Release, Client shall indicate, in writing, (i) the name of the issuer of the Release. . . which name shall be displayed to the public as the source of the Release. . .” available at <https://www.cision.com/legal/prnewswire-customer-terms-landing-page/#info2>.

- “Hey guys, so despite my best efforts of trying to avoid getting sick during this pandemic... by the time I came home I just started feeling really bad, tired, with a sore throat... noticed a dry cough and a sore throat... fever, I had a sore throat, I had a body aches and chills. I’m so excited that I found this product called Biovanta. It’s all natural which is awesome. I started seeing results immediately. And they deliver a really strong, really fast effective relief. The next day I felt 100%. The recovery was quick. It is phenomenal. Probably gonna get more of these and send them to my family and friends. I hope everyone stays safe out there and if anyone else is sick, I hope you feel better soon.” [from a video on your webpage <https://biovanta.com/collections/all-products> and the YouTube video posted on December 18, 2020 on your Biovanta channel located at <https://www.youtube.com/watch?v=tlewylf1EXo>]

You should take immediate action to address 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 address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations 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 actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. 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.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov

FTC Cease and Desist Demand: 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 products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. 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. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to \$46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section

19(b) of the FTC Act, 15 U.S.C. § 57b(b). 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 certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

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

Sincerely,

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission