



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

Date: June 26, 2020

TO: kent@nuancehealth.com – Kent New and Jennifer Sawyer New, Nuance Health, LLC
info@nuancehealth.com 244 Deer Haven Dr.
Ponte Vedra Beach, FL 32082

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://swypeshield.com> and www.swype-shield.myshopify.com on June 12, 2020, June 23, 2020, respectively. We also reviewed your social media website at <https://twitter.com/swypeshield>, where you direct consumers to your website, <https://swypeshield.com>, to purchase your products. The FDA has observed that your website offers your product “Swype Shield” 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. § 355(a). Furthermore, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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 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 websites that establish the intended use of your product and

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>). 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/>).

misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- On March 28, 2020, you reposted a tweet that says, “FACT: #COVID19 is NOT airborne. The #coronavirus is mainly transmitted through droplets generated when an infected person coughs, sneezes or speaks,” and you replied, “Use Swype!” [from a March 28, 2020 post on your Twitter website <https://twitter.com/swypeshield>]
- On March 7, 2020, you reposted a tweet that says, “I think most people aren’t aware of the risk of systemic healthcare failure due to #COVID19 . . .,” and you replied, “This is not going to happen! Swype will be back March 23rd!” [from a March 7, 2020 post on your Twitter website <https://twitter.com/swypeshield>]
- “What Is Swype Shield? Developed by Dr. Kent New, MD, PhD, with the goal of keeping his family healthy, Swype Shield is an All Natural protectant nasal gel that has been proven to kill > 99.99% of all viral upper respiratory illnesses (VURI), including Coronavirus . . . Now with over 10 years of experience using and selling Swype Shield, and hundreds of happy customers, we take pride in knowing that regular use of Swype Shield will help protect your health.” [from your website <https://swypeshield.com/pages/about>]
- “Viral upper respiratory illnesses (VURI) are the most frequent cause of acute illness in the United States with over 500 million VURI occurring annually. VURI are caused by a variety of viruses including . . . coronavirus . . . Although hand washing is important to help limit spread of these illnesses, it is an ineffective method of illness prevention because the hands only stay clean until coming in contact with another object or person contaminated with virus. . . . Using Swype Shield only 2-3x/day provides an unparalleled level of protection from VURI. By targeting the skin closest to the point of viral infection, keeping the nares clean with Swype Shield is a more effective mechanism for reducing VURI than hand washing alone. In vitro testing demonstrates the ingredients in Swype Shield kill > 99.9% of all VURI viruses tested . . . RESULTS OF INDEPENDENT LAB TESTING . . . Virus Tested . . . Coronavirus . . . SARS-associated coronavirus . . . % Reduction >99.99” [from your website <https://swypeshield.com/products/swype-shield>]

The above noted claims are supplemented by metatags used to bring consumers to your website www.swype-shield.myshopify.com through Internet searches. The metatags are:

- “Swype for Corona,” “coronavirus protection,” “Swype against Corona,” “virus killer,” “kill virus in your nose” [from your website’s metadata on www.swype-shield.myshopify.com]

In addition, your “Swype Shield” product is also misbranded under section 502(a) of the FD&C Act, 21 U.S.C. § 352(a), because your firm’s website falsely states Swype Shield has been cleared by FDA. For example, your website, www.swypeshield.com, states:

- “FDA cleared as a product intended to clean the skin, Swype Shield is an All Natural protectant nasal gel that targets the point of entry of viruses that cause upper respiratory infections – your nose!”

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 product 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. Thus, any coronavirus-related prevention or treatment claims regarding such product 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. 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,

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

Sincerely,

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission