U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

RE: CMS# 628897

Date: April 6, 2022

TO: HelloFEND@Sensory-Cloud.com – David Edwards, Sensory Cloud, Inc.
214 Cambridge Street
Suite 400
Boston, MA 02114

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://www.hellofend.com/ on March 14, 2022, and April 4, 2022, respectively. We also reviewed your social media websites at https://www.facebook.com/helloFEND/, and https://www.instagram.com/hellofend/, where you direct consumers to your website, https://www.hellofend.com/, to purchase your products. The FDA has observed that your website offers your FEND product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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, 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 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 any 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 products 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, 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/.

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

- "THIS NASAL MISTER IS A PROMISING TOOL TO BATTLE COVID-19 . . .
  With a squeeze of the device, a fine mist sprays in front of my nose. I inhale deeply, and feel the dry air of fall give way to a stream of moisture. It's a pleasant sensation for anyone who has trouble breathing as temperatures get cold. As a bonus? A Harvard study demonstrates it may have a protective effect against airborne viruses like COVID-19—similar to wearing a cotton mask.

  For the next four to five hours, I'll breathe out 50% fewer respiratory droplets that could carry disease and make other people sick. Meanwhile, any bad droplets I breathe in should be less likely to make their way down to my lungs, where COVID-19 does its worst damage." [from your webpage https://www.hellofend.com/blogs/news/this-nasal-mister-is-a-promising-tool-to-battle-covid-19]

- "A SPRAY A DAY COULD KEEP COVID AWAY . . .
  [broken image icon] nasal spray FEND new product COVID-19" [from your webpage https://www.hellofend.com/blogs/news/a-spray-a-day-could-keep-covid-away]

- "HOLIDAY GIFT GUIDE 2020: THE BEST GIFTS FOR TRAVELING SAFELY DURING THE TIME OF COVID-19 . . .
  In fact, the most important - and welcome - gifts you can give travelers right now are items that will reduce their risk of contracting Covid-19 . . .
  FEND Nasal Hygiene System [URL] . . .
  Designed by top aerosol scientist and former Harvard University professor David Edwards, FEND cleans the nasal passages by deep inhalation of a salty mist, generated by a hand-held mister device. It's scientifically proven to suppress aerosol droplets during exhalation for up to six hours, which is the average length of a cross-country flight. FEND also reduces the submicron droplets that are not captured by masks and linger in indoor environments like airplanes. It's safe to use as often as you want, and it will let you breathe easier—and healthier—during these scary times." [from your webpage https://www.hellofend.com/blogs/news/holiday-gift-guide-2020-the-best-gifts-for-traveling-safely-during-the-time-of-covid-19. This is also posted in part on your December 17, 2021 post on your social media webpage https://www.instagram.com/hellofend/]

- "GRCC HOSTS STUDY OF SPRAY THAT AIMS TO SLOW VIRUS SPREAD . . .
  Second-year Grand Rapids Community College student Sherry Sokolowski is out to help prove a breath of saltwater can help fend off COVID-19.

  'I think it's amazing that this right here in Grand Rapids and that I as a student get to be a part of this,' Sokolowski said of a test trial for an over-the-counter spray designed to slow the spread of COVID-19.

  The product, called FEND, was designed by former Harvard researcher David Edwards, an aerosol scientist." [from your webpage https://www.hellofend.com/blogs/news/grcc-hosts-study-of-spray-that-aims-to-slow-virus-spread]

- "I TESTED A HARVARD-DESIGNED NASAL SPRAY TO HELP STOP THE SPREAD OF COVID-19 . . .
  But having talked to the Harvard scientist David Edwards who created this system, dubbed the FEND, I overcome my personal embarrassment. Because if it works as intended, this invention is groundbreaking. Edwards claims that if you take just two puffs with his device, you reduce your chance of exhaling COVID-19-filled droplets by 99% for six hours—which he validated over a series of studies with 92 people. In theory, it should make your own nose and throat more resistant

to contracting COVID-19, too, by turning your throat into a sticky fly trap for the virus to keep it out of your lungs.

So I tilt my head back, and the device fires mist into the air. I breathe in deeply through my nose and—to my surprise, I actually do feel different within moments." [from your webpage https://www.hellofend.com/blogs/news/i-tested-a-harvard-designed-nasal-spray-to-help-stop-the-spread-of-covid-19]

- "We're thrilled to have been featured in Fast Company's latest. Take a look at what they have to say about the new, award-winning FEND design.
  FASTCOMPANY.COM
  This $13 nasal mister is a promising tool to battle COVID-19." [from a November 2, 2021 post on your social media webpage https://www.facebook.com/helloFEND/]

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.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused 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

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 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. 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 product 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 -S Digitally signed by Donald D. Ashley -S Date: 2022.04.06 10:08:49 -04'00'

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

Sincerely,

SERENA VISWANATHAN Digitally signed by SERENA VISWANATHAN Date: 2022.04.05 16:43:43 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission