



WARNING LETTER

Date: July 30, 2020

TO: care@mypurmist.com – Vapore LLC dba Mypurmist
1130 Burnett Avenue, Suite P
Concord, CA 94520

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.mypurmist.com/> on June 25, 2020 and July 28, 2020, respectively. The FDA has observed that your website offers Mypurmist 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 a combination product that includes coronavirus that has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The virus has been named “Coronavirus Disease 2019” (COVID-19). The Secretary of Health and Human Services (HHS) issued a declaration of a public health emergency concerning COVID-19 and mobilized the Operating Divisions of HHS to respond to the emergency.

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 mitigate, prevent, treat, diagnose, or cure COVID-19 in people that is intended to take immediate action to prevent, treat, diagnose, or cure COVID-19 in people.

Some examples of the information that establish the intended use of your product and misleadingly represents it as safe and/or effective for the treatment or prevention of COVID-19 include:

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 II, 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/>).

-
- “Novel Coronavirus / Covid-19: What to know about steam inhalation . . . [o]n this page we will provide you with guidance about steam inhalation and how to manage the symptoms of Novel Coronavirus.”
 - “Mypurmist help [*sic*] alleviate the symptoms of an upper respiratory infection such as the Novel Coronavirus (cough, runny nose, fever and breathing). The US Dept. of Homeland Security has shown that Novel Coronavirus is inactivated at a combination of 95°F temperature and >40% humidity . . . Mypurmist safely provides a temperature of 115°F and a humidity of 100%, thereby maximizing these two factors in a combination well beyond the study parameters.”
 - “Does Mypurmist help or treat pneumonia caused by Novel Coronavirus? . . . Mypurmist has not asked the FDA to be allowed to promote the use of Mypurmist for pneumonia and it has not specifically been tested for this use. However, doctors and leading healthcare institutions frequently recommend the use of warm humidified air for patients with pneumonia as palliative treatment to relieve symptoms, and improve your quality of life.”
 - “What temperature of steam does Mypurmist put out? How effective is it to help kill Novel Coronavirus in sinus? The highest temperature of Mypurmist is calibrated at 115° . . . There are no studies that measure at which temperature Novel Coronavirus specifically inactivate or stop replicating . . . But several studies have indicated that viruses inactivate/stop replicating at around 108°.”

