

Serena Viswanathan Associate Director Division of Advertising Practices United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

April 1, 2021

WARNING LETTER

VIA EMAIL TO contact@immunemist.com ImmuneMist 950 Brickell Bay Dr. Suite 2806 Miami FL 33131

Re: Unsubstantiated claims for Coronavirus prevention and treatment

To Whom It May Concern:

This is to advise you that FTC staff has reviewed your website at <u>https://www.immunemist.com</u> in April 2021. We also reviewed your social media websites at <u>https://www.facebook.com/ImmuneMist-100755105378966</u> and <u>https://www.instagram.com/immunemist</u>, where you direct consumers to your website <u>https://www.immunemist.com</u> to purchase your products. We have determined that you are unlawfully advertising that ImmuneMist Nasal Cleanse and ImmuneMist Oral Cleanse treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or cure claims on your websites include:

• On the homepage of your website <u>https://www.immunemist.com/</u> you state:

"Wash Away 99.99% of Germs and Viruses*

Help defend against viruses and germs with the worlds [sic] first comprehensive nasal and oral cleansing system....

[Depiction of a bottle of ImmuneMist Nasal Cleanse and a bottle of ImmuneMist Oral Cleanse, both of which have the text "Triple-action formula to wash away COVID" on the product label.]

Wash away harmful inhaled pathogens from your nose, mouth and throat.

Go beyond the mask with additional protection against respiratory threats. ImmuneMistTM helps your body by cleansing away pathogens before they can reach your lungs and lower respiratory tract....

[Depiction of packaging for ImmuneMist Oral Cleanse and ImmuneMist Nasal Cleanse, both of which include the following text on the box: "Triple-action formula to wash away COVID[.] Clean • Treat • Protect... Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled: ✓ Viruses..."]

Viral Loads

Viral load is the amount of virus living and replicating in your nasal and oral cavity. ImmuneMistTM helps to reduce viral load in the nose and mouth. Emerging science indicates that a reduction in viral loads is important in reducing your chance of infection. Airborne virus particles are very small and can easily bypass common face coverings and masks allowing these virus particles to enter the nose and mouth.

Viral Transmission

Viral transmission is the spread of a virus from an infected person to a healthy person. Emerging science indicates that high viral loads in the nasal and oral cavities may facilitate more rapid and extensive transmission. ImmuneMistTM is formulated to help reduce transmission among family members when physical distancing and isolation are not possible. This is helpful in multigenerational households and for family members that interact frequently with the public.

Double Layer of Protection

ImmuneMistTM is an additive layer of protection for the hand-to-nose-to-mouth cycle of contamination. This is helpful when hand washing is not possible...

[Depiction of a bar graph labeled "ImmuneMistTM removes > 99.99%* of virus particles within five seconds of contact."]

The facts[.] The most up-to-date science on nasal & oral cleansing technology."

[Carousel of seven clickable images, labeled with the following text: "Review of the use of nasal and oral antiseptics during a global pandemic"; "Treatments that target the coronavirus in the nose might help prevent COVID-19"; "Benefits and Safety of Nasal Saline Irrigations in a Pandemic – Washing COVID-19 Away"; Povidone-Iodine Use in Sinonasal and Oral Cavities: A Review of Safety in the COVID-19 Era"; "In Vitro Efficacy of a Povidone-Iodine Nasal Antiseptic for Rapid Inactivation of SARS-CoV-2"; "Chemical Considerations Related to The Dilution of Commercial 10% Povidone-Iodine For Use In The COVID-19 Pandemic"; and "See all science on nasal/oral cleansing technology."]

> • On the webpage https://www.immunemist.com/products/immunemist-nasal-cleanse where ImmuneMist Nasal Cleanse is available for purchase, you display images of the ImmuneMist Nasal Cleanse product and product packaging, which include the following statements:

"Triple-action formula to wash away COVID

Clean • Treat • Protect

ImmuneMist Nasal Cleanse

Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled:

✓ Viruses…"

Further, you state:

"ImmuneMistTM Nasal Cleanse

Help stop the spread, rinse your nasal passage to wash away germs and defend the entryway to your upper respiratory tract and lungs....

ImmuneMistTM is an additive layer of protection for the hand-to-nose-to-mouth cycle of contamination. This is helpul [sic] when hand washing is not done properly or frequent washing damages the skin.

ImmuneMistTM helps reduce transmission among family members when physical distancing and isolation are not possible. This is helpful in multigenerational households and for family members that interact frequently with the public.

ImmuneMistTM helps to reduce viral load in the nose and mouth. Emerging science indicates that a reduction in viral loads helps protect you from infection and also risk of transmission to others. Airborne virus particles are very small and can easily bypass common face coverings and masks allowing these virus particles to enter the nose and mouth.

The ImmuneMist[™] formulations (Nasal Cleanse and Oral Cleanse) have demonstrated rapid activity against Coronavirus in a laboratory setting. The formulas contain ingredients that have been scientifically substantiated to be safe and gentle, yet proven to disrupt viruses from taking hold in your nasal and oral cavity. Laboratory studies document ImmuneMist[™] effectively removed Coronavirus particles within 5 seconds of contact.

Help reduce the chance of upper respiratory infection

ImmuneMist is specially formulated by leading respiratory experts to defend your health. Its triple action formula cleans, treats and protects your nose while defending the entry point to your lungs and ultimately your bloodstream....

Go beyond the mask with additional protection against respiratory threats

ImmuneMistTM helps your body by cleansing away pathogens which can make you sick. Scientific studies have proven that cleansing is key to protecting and maintaining good respiratory health.

Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled:

✓ Viruses...

ImmuneMist's triple-action formula cleans in a unique and superior way to protect you from harmful viruses and germs.

Clean

Hypertonic saline disrupts and prevents pathogens, viruses and bacteria from occupying the nasal cavity where they can incubate and replicate in number, increasing chances of infection.

Treat

Wetting agents to help thin and remove thick nasal mucus which provide a place for pathogens to hide and replicate.

Protect

Enriched with elemental iodine. Iodine is found in pure seawater and is hostile to pathogens that can live in the nasal cavity."

• On the webpage <u>https://www.immunemist.com/products/immunemist-oral-cleanse</u> where ImmuneMist Oral Cleanse is available for purchase, you display images of the ImmuneMist Oral Cleanse product and product packaging, which include the following statements:

"Triple-action formula to wash away COVID

Clean • Treat • Protect

ImmuneMist

Oral Cleanse

Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled:

✓ Viruses…"

Further, you state:

"ImmuneMist[™] Oral Cleanse

Help stop the spread, rinse your throat and mouth to wash away germs and defend the entryway to your upper respiratory tract and lungs. Use as directed with the ImmuneMistTM Nasal Cleanse to double your layers of protection....

ImmuneMistTM is an additive layer of protection for the hand-to-nose-to-mouth cycle of contamination. This is helpul [sic] when hand washing is not done properly or frequent washing damages the skin.

ImmuneMistTM helps reduce transmission among family members when physical distancing and isolation are not possible. This is helpful in multigenerational households and for family members that interact frequently with the public.

ImmuneMistTM helps to reduce viral load in the nose and mouth. Emerging science indicates that a reduction in viral loads helps protect you from infection and also risk of transmission to others. Airborne virus particles are very small and can easily bypass common face coverings and masks allowing these virus particles to enter the nose and mouth.

The ImmuneMist[™] formulations (Nasal Cleanse and Oral Cleanse) have demonstrated rapid activity against Coronavirus in a laboratory setting. The formulas contain ingredients that have been scientifically substantiated to be safe and gentle, yet proven to disrupt viruses from taking hold in your nasal and oral cavity. Laboratory studies document ImmuneMist[™] effectively removed Coronavirus particles within 5 seconds of contact.

Help reduce the chance of upper respiratory infection

ImmuneMist is specially formulated by leading respiratory experts to defend your health. Its triple action formula cleans, treats and protects your nose while defending the entry point to your lungs and ultimately your bloodstream....

Go beyond the mask with additional protection against respiratory threats

ImmuneMistTM helps your body by cleansing away pathogens which can make you sick. Scientific studies have proven that cleansing is key to protecting and maintaining good respiratory health."

- On your Facebook page https://www.facebook.com/ImmuneMist-100755105378966, your cover photo is an image that includes the text: "wash away covid" and includes a photo of ImmuneMist Oral Cleanse product and product packaging, which includes the statements: "Triple-action formula to wash away COVID[.] Clean Treat Protect."
- On your Facebook page <u>https://www.facebook.com/ImmuneMist-100755105378966</u>, the "About" section states: "ImmuneMist[™] is the world's first comprehensive nasal and oral cleansing system to defend against viruses and germs. Laboratory results prove ImmuneMist[™] removes 99.9999% of Coronavirus particles in 5 seconds. It's [sic] formula is gentle, safe and easy to use. It is a scientific fact that many infections start with Covid-19 virus being inhaled into the nose where it incubates and increases in number. Within 3-5 days your [sic] may get sick and also spread the virus to friends and loved ones. Using ImmuneMist[™] as directed, cleanses your nose and mouth of viral particles aiding your body's protection."
- In an Instagram post dated March 3, 2021, you state: "Available now! ImmuneMist Oral Spray clean [sic], treats and protects your oral cavity while defending your upper respiratory tract. #virusprotection #maskup #virus." This post includes an image of ImmuneMist Oral Cleanse product and product packaging, with the same text as described above.
- In another Instagram post dated March 3, 2021, you state: "ImmuneMist Nasal Cleanse helps wash away germs and viruses keeping your nasal passage clean from foreign pathogens. #virus #virusprotection #covid_19." This post includes an image of ImmuneMist Nasal Cleanse product and product packaging, with the same text as described above.
- In another Instagram post dated March 3, 2021, you state: "Meet the first comprehensive nasal and oral cleansing system to defend against viruses and germs. Laboratory results prove ImmuneMist removes > 99.9999% of Coronavirus particles within 5 seconds. #virus #socialdistancing #maskup." This post includes an image with the text: "wash away covid."
- In another Instagram post dated March 3, 2021, you state: "Healthcare professionals agree: washing your nose/mouth is just as important as washing your hands! #staysafe #wearamask #healthcareworkers #publichealth." This post includes an image with the text: "Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled: ✓viruses..."

- In another Instagram post dated March 3, 2021, you state: "Triple-action formula to clean, treat and protect against germs and viruses. #publichealth #healthcareheroes #vaccine #covid..." This post includes an image of ImmuneMist Nasal Cleanse product packaging, which includes the text: "Triple-action formula to wash away COVID[.] Clean Treat Protect" and "Clinically-tested ingredients and Doctor-endorsed to help protect against inhaled: ✓Viruses..."
- In another Instagram post dated March 3, 2021, you state: "Reduce viral load and prevent transmission when you wash your oral/nasal passage with ImmuneMist. #vaccine #healthcareworkers #nurses #firstresponders #healthcare #pediatrics #frontlineworkers." This post includes an image with the text: "Wash away 99.99% of germs and viruses."

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 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.

You are also advised to review all other 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. 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 \$43,792 per violation.

Within 48 hours, please send a message to Richard Cleland via electronic mail at <u>rcleland@ftc.gov</u> 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.

Very truly yours,

Serena Viswanathan Associate Director

Cc: Shopify *via email to* <u>gov-inquiries@shopify.com</u> Facebook and Instagram *via email to* <u>consumerpolicy@fb.com</u>