



Serena Viswanathan
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

December 14, 2021

CEASE AND DESIST DEMAND

VIA EMAIL TO info@navage.com and support@navage.com
Mr. Martin R. Hoke, President and Founder
RhinoSystems, Inc.
1 American Road, Suite 1100
Brooklyn, Ohio 44144

Re: Unsubstantiated claims for Coronavirus prevention and treatment

Dear Mr. Hoke:

This is to advise you that FTC staff has reviewed your website at <https://www.navage.com> in December 2021. We also reviewed your social media websites at <https://www.facebook.com/Navage4Life/> and <https://www.youtube.com/user/NavageRocks>, where you direct consumers to your website, <https://www.navage.com>, to purchase Naväge nasal irrigation products. We have determined that you are unlawfully advertising that Naväge products treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or treatment claims include:

- In an email sent to consumers on September 17, 2021 with the subject line, “**Clinical Trial Preprint: Covid and Twice Daily NASAL IRRIGATION,**” you state:

“SUMMARY: A clinical study using nasal irrigation was recently published on [MedRXiv.com](https://www.medrxiv.com) [link to <https://www.medrxiv.org/>], a non peer-reviewed site for new medical research that is overseen by Yale University and the British Journal of Medicine. The primary result is that individuals who tested positive for Covid and immediately began using nasal irrigation twice-a-day were 8.4 times less likely to be hospitalized or die than those who did not....

Dear Naväge Enthusiast,

I’m writing to share some exciting news about the preprint publication of a recent scientific study.

Please note that a preprint has yet to be evaluated by the scientific community through the peer review process, and it may undergo future alterations.

In July, 2020, RhinoSystems, the maker of Naväge, was asked to support a clinical trial designed to test the theory that people who get Covid will have better outcomes if they immediately begin using nasal irrigation twice-a-day, compared to those who don't. The primary measured outcomes were hospital admissions and death. The results are in, and they are so very encouraging.

In short, Covid-positive individuals who immediately began using nasal irrigation twice-a-day were 8.4 times less likely to be hospitalized or die than those who did not.

There are more details and a link to the study below. But first, here's a quick review of the basic science behind nasal irrigation:

1. The vast majority of airborne germs enter your body through the nose.
2. Your nose is the body's air filter, the first line of defense against allergens, bacteria, and viruses....
3. Nasal irrigation reduces viral loads by mechanically flushing mucus and germs out of the nasal cavity.... In addition, researchers theorize that regularly cleaning the nasal cavity makes it harder for spikey viruses to bind themselves to ACE2 receptors. All of this helps your body's immune system do its job of defending against illness!
4. Germs colonize and grow in the nasal cavity over time; it doesn't happen immediately. The actual process also appears to vary a great deal from one person to another. The important point is that it takes time, i.e., hours – exactly how many, no one knows just yet – for the spikey viruses to bind themselves to receptors. This implies that irrigating twice-a-day may be the key. In any event, using Naväge twice-a-day has always been our recommendation to maximize its healthy benefits, just like brushing your teeth.

CLINICAL TRIAL SUMMARY: Trial participants came from individuals age 55+ who, feeling ill, went to a clinic in Augusta, Georgia for a Covid test. Those who tested positive were asked to participate in a clinical trial in which they would use nasal irrigation twice a day for 30 days. Approximately half of the participants used Naväge Nasal Care. A total of 79 participants were enrolled from September through December, 2020. Their outcomes were compared to the outcomes for a control group not using nasal irrigation....

LINK TO MEDRXIV PREPRINT: [Rapid initiation of nasal saline irrigation to reduce morbidity and mortality in COVID+ outpatients: a randomized clinical trial compared to a](#)

[national dataset](https://www.medrxiv.org/content/10.1101/2021.08.16.21262044v2) [link to <https://www.medrxiv.org/content/10.1101/2021.08.16.21262044v2>]

PRIMARY RESULT: Clinical trial participants were 8.4 times less likely to be hospitalized or die than non-participants.

The significant, *8-fold* reduction in hospitalization rates by participants who used nasal irrigation is an exceptionally positive result. To put this in context, consider the [anti-viral drug by Regeneron](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19) [link to <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>] received FDA Emergency Use Approval last November for only a 3-fold reduction in hospitalization rates....

I'm sharing this good news with you in the hope that if you do not already, you will give serious consideration to becoming a twice-a-day Naväge user yourself. I can think of very few things you could do for yourself or those you love that are as simple and healthy.

On a more personal and purely anecdotal note, namely the experience of two, twice-a-day Naväge users: Throughout the pandemic, RhinoSystems has been up, running, and manufacturing Naväge Nose Cleaners and SaltPods, and during that time neither my wife, Maria, nor I have missed a day of work due to illness – thanks be to God and knock on wood!

Best regards,
Martin...
Martin R. Hoke
President and Founder...

- In an email sent to consumers on September 20, 2021 with the subject line, “**Just in case you missed it: Twice-A-Day NASAL IRRIGATION, a Covid Clinical Trial Preprint,**” you repeated all of the claims described above.
- In a July 21, 2021 video titled “Naväge 2021 Commercial – So Many Good Things,” available at <https://www.youtube.com/watch?v=G5zmTLuTCs>, you state:

“The pandemic’s reminded us that germs invade through your nose, the body’s natural air filter for trapping allergens, dirt, and viruses. But how do you clean it? It’s easy with Naväge. Naväge uses powdered suction to flush out all the stuff that causes congestion, allergies, colds, and worse. When your nose is clean, so many good things happen...” This video begins with an animation of round red objects with spikes, clearly identifiable as depictions of coronavirus, entering an individual’s nose.

- In an April 26, 2021 video titled, “Navage :30 Commercial How Clean Is Your Nose?,” available at https://www.youtube.com/watch?v=iJT_5R5eD2E, you state:

“How clean is your nose? Airborne germs and allergens invade through your nose, the body’s air filter and first line of defense. You wash your hands and brush your teeth, but how do you clean your nose? With Naväge. Naväge uses powered suction to flush out pollen, mucous, bacteria, and viruses....” This video also includes an animated depiction of coronavirus (round red objects with spikes) entering an individual’s nose.

You also posted a French version of this video on April 27, 2021, that is available <https://www.youtube.com/watch?v=YfxNRBx58uk>.

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 and desist making all such claims.

You are also advised to review all other claims for your products and immediately cease and desist 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. 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 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 a message to Mr. Richard Cleland (Assistant Director) 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.

Very truly yours,

Serena Viswanathan
Associate Director
Division of Advertising Practices

cc: youtube-gov-support@google.com