



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

Serena Viswanathan
Associate Director
Division of Advertising Practices

April 1, 2021

WARNING LETTER

VIA EMAIL TO questions@neilmed.com
NeilMed Pharmaceuticals, Inc.
601 Aviation Blvd.
Santa Rosa, California 95403

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 <https://www.neilmed.com/> in March 2021. We also reviewed your social media websites at <https://www.facebook.com/sinusrinse/> and <https://www.instagram.com/neilmed/> where you direct consumers to your website <https://www.neilmed.com/> to purchase your products, which are also available for purchase directly on Facebook and Instagram. We have determined that you are unlawfully advertising that your nasal irrigation products 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 <https://www.neilmed.com/>, you have a prominent image carousel at the top of the page. The first image in the carousel states: “Saline Nasal Irrigation and COVID-19” and includes an image of various NeilMed nasal case products.

Consumers who click on this image in the carousel are taken to <https://www.neilmed.com/usa/covid19.php>, a webpage titled “COVID-19: We Are Here To Help.” This webpage is also accessible from other pages on your website by clicking on the “Our Response to COVID-19” option in your website navigation menu, prominently displayed in red-colored text. This page contains three tabs, including one labeled “Saline Nasal Irrigation and COVID-19.” Consumers who click on that tab see the following text:

“Many of you have been asking whether nasal irrigation could assist in preventing or easing the symptoms of COVID-19. Our answer is that although evidence is not

conclusive, several research articles have found nasal irrigation to be especially beneficial during this pandemic.

One study found that hypertonic saline nasal irrigation and gargling reduced the duration of the coronavirus upper respiratory tract infection by an average of 2.5 days, and reduced household transmission by 35%. Patients who performed hypertonic saline nasal irrigation and gargling recovered from COVID-19 symptoms (blocked nose, cough, and hoarseness of voice) several days sooner than those who did not. The study suggested that nasal irrigation and gargling may be safe and effective in treating those infected with COVID-19¹.

An article published by JAMA also suggested that nasal saline irrigation may reduce viral severity and transmission. By flushing out mucus, nasal irrigation may also remove viral particles prior to active infection. The authors recommended that it would be especially beneficial for patients and healthcare workers especially should perform saline nasal irrigation².

Additional studies are underway to understand the potential benefits of nasal irrigation in treating and preventing COVID-19. NeilMed is pleased that the scientific community is continuing to examine this issue and hopes that more good news will be forthcoming. We will keep you updated as developments arise. For more information, please visit our Medical Articles and Literature page at <http://www.neilmed.com/usa/med-articles.php>.

¹ Farrell, Nyssa F., Cristine Klatt-Cromwell, and John S. Schneider. ‘Benefits and Safety of Nasal Saline Irrigations in a Pandemic—Washing COVID-19 Away.’ JAMA Otolaryngology–Head & Neck Surgery (2020)

² Ramalingam, Sandeep, et al. ‘Hypertonic saline nasal irrigation and gargling should be considered as a treatment option for COVID-19.’ Journal of Global Health 10.1 (2020).”

- On the webpage at <https://www.neilmed.com/usa/med-articles.php>, titled “GENERAL MEDICAL ARTICLES & LITERATURES,” the first two articles listed are “BENEFITS AND SAFETY OF NASAL SALINE IRRIGATIONS IN A PANDEMIC—WASHING COVID-19 AWAY” [hyperlinked to <https://www.neilmed.com/usa/article-benefits-and-safety-of-nasal-saline-irrigations.php>] and “HYPERTONIC NASAL IRRIGATION AND COVID-19” [hyperlinked to <https://www.neilmed.com/usa/article-hypertonic-nasal-irrigation-and-covid-19.php>].

- On the webpage at <https://www.neilmed.com/usa/article-benefits-and-safety-of-nasal-saline-irrigations.php>, titled “BENEFITS AND SAFETY OF NASAL SALINE IRRIGATIONS IN A PANDEMIC—WASHING COVID-19 AWAY,” you state:

“The coronavirus disease 2019 (COVID-19) pandemic has ignited interest in viral transmission and prevention owing to the significant morbidity and mortality associated with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Investigations into SARSCoV- 2 pathophysiology suggest that, similar to other viral upper respiratory infections, infection occurs primarily in the nasal and nasopharyngeal mucosa with high viral loads early in disease.... Nasal irrigations may play a role in reducing viral severity and further transmission....

The nasal lining serves an important role in the innate immune system, providing a primary defense against inhaled viruses, bacteria, and other particulates. This lining, consisting of a superficial mucus layer atop an aqueous base, traps inhaled particulates that are then propelled by underlying cilia into the nasopharynx. They are ultimately driven into the gastrointestinal system, where they are destroyed. Topical nasal rinses take advantage of this secretory lining in multiple ways. First, nasal rinses physically disrupt the viscous surface layer, removing the mucus and its associated particulate matter. Additionally, the presence of nasal saline helps to increase hydration of the deeper aqueous layer, simultaneously improving the underlying ciliary beat frequency and reducing local inflammatory mediators. This can be particularly helpful during a viral respiratory infection, in which there is resultant mucociliary dysfunction and mucostasis that occurs secondary to the inflammatory response....

SARS-CoV-2 is a highly virulent respiratory virus with significant presence in the nasal and nasopharyngeal mucosa. Hypertonic nasal saline, which facilitates mucociliary clearance, likely decreases viral burden through physical removal. Other additives, such as povidone-iodine, may aid in eliminating viral particles within the nasal cavity and nasopharynx prior to active infection.... Emerging research is expected to shed further light on saline irrigation’s protective and therapeutic effect on COVID-19....”

- On the webpage at <https://www.neilmed.com/usa/article-hypertonic-nasal-irrigation-and-covid-19.php>, titled “HYPERTONIC NASAL IRRIGATION AND COVID-19,” you state:

“Recently, a study came to our attention that supports the theory that nasal irrigation may be beneficial to patients infected with COVID-19. You can review the study here:

<http://www.jogh.org/documents/issue202001/jogh-10-010332.htm>.

In the study funded by Edinburgh and Lothians Health Foundation, findings suggest that hypertonic saline nasal irrigation helps to minimize the duration of coronavirus infection and should be considered as a viable treatment option for COVID-19.

The study included 66 adults infected with coronavirus upper respiratory tract infection (URTI) within 48 hours of study onset. They conducted daily hypertonic nasal irrigation sessions at home when needed (a maximum of 12 times daily). Compared with a control group, these subjects experienced reduced time of infection by an average of 1.9 days, decreased over-the-counter medication use by 36%, and other positive results.

Furthermore, NaCl (salt) has been found to have antiviral effects inhibiting viruses such as human coronavirus. A large concentration of the coronavirus infection is found in the upper respiratory tract, and hypertonic saline nasal irrigation has been shown to reduce symptoms as well as infection time in subjects. The study strongly suggests that hypertonic saline nasal irrigation and gargling should be considered as a safe, globally successful option to help treat coronavirus and its symptoms.

Although nasal irrigation as a treatment for COVID-19 has not been studied thoroughly, we view this as good news. We have always advocated nasal irrigation to promote good health and are pleased that the scientific community has begun to examine the use of nasal rinsing in connection with the coronavirus.”

- In Facebook and Instagram posts on August 18, 2020, you state: “Benefits and Safety of Nasal Saline Irrigations in a Pandemic—Washing COVID-19 Away. Read the article, visit <https://bit.ly/3iQQjki>.” The shortened URL included in this post leads to <https://www.neilmed.com/usa/article-benefits-and-safety-of-nasal-saline-irrigations.php>, described above.
- In a Facebook post on June 30, 2020, you state: “Hypertonic Nasal Irrigation and COVID-19. Recently, a study came to our attention that supports the theory that nasal irrigation may be beneficial to patients infected with COVID-19. Visit <https://bit.ly/3eTG11q>.” The shortened URL included in this post leads to <https://www.neilmed.com/usa/article-hypertonic-nasal-irrigation-and-covid-19.php>, described above.

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.

NeilMed Pharmaceuticals, Inc.

April 1, 2021

Page 5

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 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.

Very truly yours,

Serena Viswanathan
Associate Director

cc: Facebook and Instagram *via email*
consumerpolicy@fb.com