U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

16 June 2021

Robert Housman, Esq.
Partner
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Dear Mr. Housman:

Thank you for your follow-up email, dated May 3, 2021, to the Centers for Disease Control and Prevention's (CDC's) Chief Medical Officer Dr. Mitchell Wolfe regarding the use of nasal sprays to combat coronavirus disease 2019 (COVID-19). I am responding to the points outlined in your email on behalf of Dr. Wolfe.

Issuing Guidance:

Generally, before issuing guidance, CDC evaluates available evidence, the quality of available and pertinent evidence and studies, and the benefits and potential harms from the intervention being evaluated. Specific to the pandemic, CDC continues to monitor scientific and case studies of potential medical products and non-pharmaceutical interventions to help treat and prevent infections of SARS-CoV-2, the virus that causes COVID-19, and improve COVID-19 outcomes. This includes potential off-label use of certain medical products and devices to reduce viral loads and shedding. CDC, however, generally does not make recommendations for use of products or interventions to alleviate symptoms. CDC also generally does not issue guidance regarding investigational uses of medical products and devices and will only issue guidance on the use of a medical countermeasure to help combat COVID-19 once an Emergency Use Authorization (EUA) is issued by the U.S. Food and Drug Administration (FDA). This is because FDA conducts a more thorough scientific review of the medical products for off-label use.

FDA's Pending Review of Xlear's Product:

CDC is aware of the previous and current pre-EUA submissions by Xlear, Inc. of its nasal spray[1] to the FDA.[2] CDC defers to the FDA regarding any EUA approvals of off-label use of medical products, including during public health emergencies. An EUA is necessary in this instance since the use of nasal spray to treat or alleviate symptoms of COVID-19 would be an off-label use. The EUA process ensures a thorough review of the available scientific evidence to support the use of a medical countermeasure, such as a biologic, pharmaceutical drug, or medical device.

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[1] https://xlear.com/

[2] https://www.businesswire.com/news/home/20210324005241/en/Xlear-Submits-COVID-19-Pre-Emergency-Use-Authorization-Request-with-FDA-Regarding-Use-of-Xlear-Nasal-Spray-in-Help-in-Combating-SARS-CoV-2

This process also provides invaluable information for clinicians on the use of the medical countermeasure, including suggestions for best uses, contraindications and other risks, and potential adverse events, as well as a system for reporting them. CDC will continue to monitor this situation and awaits the final decision by FDA. As mentioned above, CDC will only consider issuing relevant guidance on the use of a medical countermeasure available to potentially treat or prevent COVID-19 once an EUA is issued.

NIH Treatment Guidelines:

CDC is aware of ongoing clinical trials being conducted to evaluate the efficacy of Xlear nasal spray for use against COVID-19.[3] As previously mentioned, CDC generally does not make recommendations for use of products to alleviate symptoms or specific treatments for diseases. CDC strongly encourages consultation with the *COVID-19 Treatment Guidelines* published by the National Institutes of Health for information on specific treatment and symptom relief options.[4] The treatment and management recommendations in these guidelines are based on scientific evidence and expert opinion. CDC also looks to these and other in-depth studies to provide additional context in areas where other studies may be lacking, or additional information is needed, prior to issuing or updating our guidance.

Clinical Trials Involving Nasal Sprays:

For example, in the small, open-label and randomized study by Kyle Kimura, et. al., mentioned in your additional correspondence regarding this petition,[5] the authors recommend the use of nasal irrigation with hypertonic saline or saline with surfactant only for COVID-19 symptom alleviation. The study presents no hard evidence of efficacy in terms of viral load reduction from nasal decolonization and mentions the potential to further spread viral particles. Assessment of the collected nasal swabs from participants for SARS-CoV-2 ribonucleic acid (RNA) levels would be informative, as well as data from a larger randomized controlled study, to provide stronger evidence that the intervention is effective. If further data is released regarding this work or other studies on viral load reduction, CDC will consider this additional scientific evidence when available to determine updates to our recommendations.

While nasal sprays and irrigation are generally safe, they are not without risk. There have been cases of serious infections associated with sinus irrigation from Neti-pots or other exposure to tap water or use of adulterated products. The Kimura study also mentions a potential drawback of the intervention, as the procedure could generate droplets and contaminate surrounding surfaces, which could lead to potential SARS-CoV-2 transmission, especially if regular disinfection is not performed.

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[3] https://clinicaltrials.gov/ct2/show/NCT04610801

[4] https://www.covid19treatmentguidelines.nih.gov/

[5] Kimura KS, Freeman MH, Wessinger BC, et al. Interim analysis of an open-label randomized controlled trial evaluating nasal irrigations in non-hospitalized patients with coronavirus disease 2019. *Int. Forum Allergy Rhinol.* 2020;10:1325-1328. https://doi.org/10.1002/alr.22703

Administrative Procedure Act Claims:

As stated previously, the petition's request does not satisfy the definition of a rule under the Administrative Procedure Act and is therefore denied. Moreover, upon receipt of a petition, an agency is not required to grant the request; it is only mandated to consider the petition and respond within a reasonable timeframe.[6] CDC responded to your request on April 27, 2021, and provided a brief statement of grounds for the denial, which is all that is required of the agency.[7] Further, because of the reasons outlined above, CDC will not be issuing guidance on the use of nasal spray at this time.

Ongoing critical review of scientific evidence is essential to ensure CDC guidance documents are based on the best available information, whether regarding recommendations for well-understood medical conditions and practices or for use when responding to novel and emerging threats. CDC will continue to monitor the scientific literature on potential medical and non-pharmaceutical interventions to help prevent and treat infections related to COVID-19. CDC will await the result of the FDA's EUA review of Xlear's nasal spray product prior to considering whether to issue guidance.

Thank you for your interest in this ongoing response. We appreciate your support as we all work together to fight COVID-19.

Sincerely,

Sandra Cashman, MS
Executive Secretary
Office of the Chief of Staff, CDC

[6] U.S.C. Sections 553(e),555(b), and 555(e).
[7] CDC response letter dated April 27, 2021.