U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: March 7, 2022

TO: infor@viraldine.com

Viraldine, LLC
311 Lake Street
Elmira, NY 14901

RE: Unapproved New Drug 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://viraldine.com/ on December 21, 2021 and March 1, 2022, respectively. The FDA has observed that your website offers non-alcohol-based antiseptic products[1] for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under sections 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). These violations are described in more detail below.

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[3] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19 that subsequently has been extended.[4] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your labeling that establish the intended use (as defined in 21 CFR 201.128) of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include, but may not be limited to, the following:

> "**INTRANASAL POVIDONE-IODINE EFFECTIVELY LIMITS COVID-19 SPREAD, FINDS STUDY HTTPS://PUBMED.NCBI.NL**" [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

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[1] Your non-alcohol-based antiseptic drug products include 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY.

[2] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

[3] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists. (originally issued on Jan. 31, 2020., and subsequently renewed) *available* at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx).

[4] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available* at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

"**POVIDONE IODINE (PVP-I) ORO-NASAL SPRAY: AN EFFECTIVE SHIELD FOR COVID-19 PROTECTION FOR HEALTH CARE**" [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"**Results:** All concentrations of nasal antiseptics and oral rinse antiseptics evaluated completely inactivated the SARS-CoV-2. **Conclusions:** Nasal and oral PVP-I antiseptic solutions are effective at inactivating the SARS-CoV-2 at a variety of concentrations after 60-second exposure times. The formulations tested may help to reduce the transmission of SARS-CoV-2 if used for nasal decontamination, oral decontamination, or surface decontamination in known or suspected cases of COVID-19." [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"The researchers came out with the following findings- 1. Povidone-iodine nasal antiseptics at concentrations (0.5%, 1.25%, and 2.5%) completely inactivated SARS-CoV-2 within 15 seconds of contact…" [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"Hence, the authors concluded that 'Povidone-iodine nasal antiseptic solutions at concentrations as low as 0.5% rapidly inactivate SARS-CoV-2 at contact times as short as 15 seconds. Intranasal use of PVP-I has demonstrated safety at concentrations of 1.25% and below and may play an adjunctive role in mitigating viral transmission beyond personal protective equipment.'" [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"SARS-CoV-2 virus was completely inactivated by PVP-I oral antiseptic rinse in vitro, at the lowest concentration of 0.5 % and at the lowest contact time of 15 seconds. . ." [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"Recent evidence has confirmed that 0.5% povidone iodine (PVP-I) mouthrinse/gargle for 30 s can reduce SARS-CoV-2 virus infectivity to below detectable levels. PVP-I can even interrupt SARS-CoV-2 attachment to oral and nasopharyngeal tissues and lower the viral particles in the saliva and respiratory droplets. Thus, the use of PVP-I mouthrinse as a prophylactic measure has been advocated across the globe to reduce disease transmission. . . [from your website https://viraldine.com/faqs-%26-pvp-i-studies]

"4 Hour Maximum Protection" [from product labels on your website https://viraldine.com/shop]

Based on the above claims and statements, your topical antiseptic[5] and oral antiseptic[6] products are "drugs" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended for use as consumer topical antiseptics. 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY is intended for use as a consumer oral antiseptic.

These consumer topical antiseptics and oral antiseptic products are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for these products, as

[5] 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY
[6] 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY

further described below) or under other exceptions not applicable here. No FDA-approved applications pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these drug products, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that your drug products are GRASE for use under the conditions suggested, recommended, or prescribed in their labeling. Accordingly, these drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

We note that OTC topical and oral antiseptic products had been the subject of rulemakings under the Agency's OTC Drug Review. In particular, consumer topical antiseptics were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) (Consumer Antiseptic Rubs Proposed Rule). Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub.

Oral antiseptics were addressed in a tentative final monograph (TFM) entitled "Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products"; Proposed Rule, 59 FR 6084 (February 9, 1994) (Oral Antiseptics Proposed Rule). Over the course of this rulemaking for oral antiseptics, povidone iodine at 0.5%, when labeled for short-term use (not to exceed 7 days), was classified as Category III for use as an OTC oral antiseptic, because additional effectiveness data are needed to support a determination that a product containing this active ingredient would be GRASE for use as an OTC oral antiseptic.

Section 505G of the FD&C Act governs nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they meet the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements.

However, your non-alcohol-based antiseptic products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, nor any other TFM, proposed rule, or final rule and do not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505.[7]

Specifically, your labeling claims, suggesting that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL

[7] We note that 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY also do not conform to any temporary policy FDA has implemented during the public health emergency. In March 2020, the Agency published three guidance documents to provide regulatory flexibility to certain firms to help meet the demand for alcohol-based hand sanitizer during the COVID-19 public health emergency (PHE). Because your non-alcohol-based consumer antiseptic products are not consistent with the formulations described in these guidances, they do not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act. Additionally, on December 31, 2021 these guidances were withdrawn, and firms must cease distribution, by March 31, 2022, of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. See, 86 FR 56960, October 13, 2021.

SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are effective in shortening the duration of infection and preventing infection or disease from the novel coronavirus that causes COVID-19, go beyond merely describing the general intended use of an antiseptic as set forth in the 1994 TFM and the Oral Antiseptics Proposed Rule.[8] In addition, your labeling claims, suggesting that your non-alcohol-based antiseptic products provide up to 4 hours of efficacy against the novel coronavirus that causes COVID-19, are not permitted under the 1994 TFM, the Oral Antiseptics Proposed Rule, or any of the amendments to the TFMs discussed above. Time-specific extended efficacy claims, especially when related to serious-disease related pathogens, may lead to a false sense of security for the general public that may result in infrequent hand washing or the substitution of these products for protective gloves and clothing, which are the principal methods for protecting against the spread of diseases caused by pathogenic microorganisms. As a result, these products may give users the false impression that they need not rigorously adhere to interventions such as social distancing and exercising good hygienic practices that have been demonstrated to curb the spread of COVID-19. Users who do not follow these interventions are at increased risk for contracting COVID-19 and for spreading disease if they have been exposed to the virus, thereby prolonging the pandemic and increasing its associated morbidity and mortality.

In addition, according to the product labeling, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY are intended to be applied inside the nostrils. Consumer antiseptic products intended for administration inside the nostrils are not permitted under the 1994 TFM, as further amended by the Consumer Antiseptic Rubs Proposed Rule.[9]

Furthermore, 1.5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, 1% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, .5% POVIDONE IODINE USP ANTISEPTIC NASAL SPRAY, and 1.5% POVIDONE IODINE USP ANTISEPTIC THROAT SPRAY are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but do not comply with the requirements for marketing under that section and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355.

You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA. **Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the

[8] The 1994 TFM covers consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443. The Oral Antiseptics Proposed Rule covers oral antiseptics that are indicated for use in first aid to help decrease bacterial contamination in minor cuts, minor scrapes or minor oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury and for use by health care professionals for preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction. 59 FR at 6121-22.

[9] The 2016 Consumer Antiseptic Rubs Proposed Rule covered consumer antiseptic products intended for use without water. Under the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, only consumer topical antiseptic products intended for use on the hands without water are permitted. Products intended for other areas of the body such as the nose are not permitted.

treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action. We note however, removal from the published list should not be interpreted to mean that you have properly addressed all other violations for your products and that you are free to proceed with their continued marketing.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your products referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

FTC Cease and Desist Demand: In addition, 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, including, when appropriate, well-controlled human clinical studies, 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. 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 $46,517 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 an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, 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.

Sincerely,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -S
Date: 2022.03.07 10:26:01 -05'00'

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

Digitally signed by SERENA VISWANATHAN
Date: 2022.03.04 15:08:00 -05'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission