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

“**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

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-kill studies [illegible]

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

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
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