



WARNING LETTER

Date: December 18, 2020

TO: info@rowpar.com – James Ratcliff, CEO, Rowpar Pharmaceuticals, Inc.
info@closys.com 16100 N. Greenway Hayden Loop #400 Scottsdale, AZ 85260

RE: Unapproved and Misbranded 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 www.closys.com on October 22, 2020, and December 7, 2020, respectively. We also reviewed your social media websites at www.facebook.com/CloSYS/ and www.twitter.com/closys, where you direct consumers to your website, www.closys.com, to purchase your products. The FDA has observed that your website offers CloSYS Oral Spray, CloSYS Non-Irritating RINSE UN-flavored for ULTRA SENSITIVE Mouths, and CloSYS Non-Irritating RINSE Mildly Flavored for SENSITIVE Mouths products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ 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 section 502 of the FD&C Act, 21 U.S.C. § 352. 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).

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.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³ 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 such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

¹ As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

² Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>).

³ President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

Some examples of the claims on your websites that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Lab Tests: CloSYS Oral Rinse Eliminated COVID-19 Virus up to 98.4% in 30 seconds” [from an August 31, 2020 post on your social media website www.facebook.com/CloSYS/].
- “**Lab Test: CloSYS Ultra Sensitive Rinse, CloSYS Sensitive Rinse, & CloSYS Oral Spray Reduced COVID-19 virus up to 98.4% in 30 seconds.** ... As CloSYS is an excellent antimicrobial for oral care we initiated lab tests to understand if our patented formula might be helpful reducing the viral load of saliva thus potentially lowering the transmission of the COVID-19 virus (*not to be confused with the more common less harmful human coronaviruses*).” [from your website www.closys.com].
- “Today more than ever...MOUTH HEALTH IS ESSENTIAL Tested On: COVID-19 Virus” This accompanies a graphic with a depiction of your CloSYS Non-Irritating RINSE Mildly flavored for SENSITIVE Mouths, CloSYS ORAL SPRAY, and CloSYS Non-Irritating RINSE UN-flavored for ULTRA SENSITIVE Mouths products. [from your website www.closys.com].
- “Results from an in vitro lab study with CloSYS Oral Spray and CloSYS Ultra Sensitive Oral Rinse proved effective in eliminating the SARS-CoV-2 (COVID-19 virus) viral load by 98.4% within 30 seconds.” This accompanies a graphic with depictions of your CloSYS ORAL SPRAY and CloSYS Non-Irritating RINSE UN-flavored for ULTRA SENSITIVE Mouths and CloSYS Non-Irritating RINSE Mildly Flavored for SENSITIVE Mouths products and the text “TESTED ON COVID-19 VIRUS.” [from a November 18, 2020 post on your social media website www.facebook.com/CloSYS/].
- “...CloSYS Ultra Sensitive Rinse may be able to join the fight and that is something for dental professionals to truly ‘swish around’ before suiting up in the fight of the SARS-CoV-2 virus.” [from an October 30 post on your social media website www.facebook.com/CloSYS/ and an October 30, 2020 tweet on your social media website www.twitter.com/closys].
- “We have some exciting news about the first step lab results of CloSYS Oral Rinse and its effect on SARS CoV-2, the novel #coronavirus that causes COVID-19.” [from a September 4, 2020 post on your social media website www.facebook.com/CloSYS/].
- “**Lab tests confirm CloSYS Oral Rinse eliminates COVID-19 virus by up to 98.4% in 30 seconds** ‘These are exciting and potentially groundbreaking findings,’ said CEO of Rowpar Pharmaceuticals, Jim Ratcliff. ‘We know that the COVID-19 virus can be transmitted from person to person through spray droplets from the mouth, so this is an important first step in determining whether our oral care products can make a significant impact in reducing the chances of becoming ill or infecting others. There is a lot more to learn as we follow the science, but it’s a very positive start for our rinse formula.’” [from a September 15, 2020 post on your social media website www.facebook.com/CloSYS/].
- “CloSYS Oral Spray and CloSYS Sensitive Oral Rinse proved effective in eliminating the SARS-CoV-2 viral load by 98.4% within 30 seconds. These results show identical to our earliest lab study with our Ultra Sensitive Oral Rinse and #COVID-19 virus.” [from a November 18, 2020 tweet on your social media website www.twitter.com/closys].
- “Lab tests confirm @CloSYS Oral Rinse eliminates #COVID-19 virus by up to 98.4% in 30 seconds.” [from a September 3, 2020 retweet on your social media website www.twitter.com/closys].

You should take immediate action to correct 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 and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an**

email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to correct 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 immediately correct the violations cited in this letter 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 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 cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. 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 are subject to detention and refusal of 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 product(s) 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.

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 product identified above. Thus, any coronavirus-related prevention or treatment claims regarding such product 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. 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 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.

Sincerely,

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

Sincerely,

Serena Viswanathan
Acting Associate Director
Division of Advertising Practices
Federal Trade Commission