



WARNING LETTER

DATE: May 27, 2021

TO: oclo@usa.com – Ricardo Garcia
OCLO LLC
220 SW 9th Ave, #506
Hallandale, FL 33009

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) reviewed your website at the Internet address <https://dioxidodecloro.us> on April 15, 2021 and the Federal Trade Commission (FTC) reviewed the site as it appeared on that date. We also reviewed your social media website at <https://facebook.com/Hallandale.Beach.2018/> where you direct consumers to your website, <https://dioxidodecloro.us>, to purchase your products. Additionally, we reviewed your product listings on your eCrater storefront, which you operate under the name, OCLO. The FDA has observed that your website previously offered, and your eCrater storefront continues to offer, various chlorine dioxide products, including “OCLO 3000,” 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, there was a Presidential declaration of 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

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, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ 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/>.

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 website 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:

- “Dióxido de Cloro . . . terapia alternativa efectiva contra el COVID-19, tratamiento de infecciones, algunas enfermedades autoinmunes y en terapias oxidativas para el fortalecimiento del sistema inmunológico.” “Chlorine Dioxide... effective alternative therapy against COVID-19, treatment of infections, some autoimmune diseases and oxidative therapies for strengthening the immune system.” (Translated) [from your eCrater storefront <https://oclo.ecrater.com/index.php>]
- “El Dióxido de cloro en solución acuosa (CDS) es un potente agente oxidante antiséptico, que combate numerosas infecciones patógenas. Además, entre sus beneficios, fortalece el sistema inmune por oxigenación celular y se ha comprobado su eficacia en el tratamiento y prevención contra el actual CORONAVIRUS.” “Chlorine dioxide in aqueous solution (CDS) is a powerful antiseptic oxidizing agent, which fights numerous pathogenic infections. In addition, among its benefits, it strengthens the immune system by cellular oxygenation and its effectiveness in the treatment and prevention against the current CORONAVIRUS has been proven.” (Translated) [from your product listing on your eCrater storefront <https://oclo.ecrater.com/p/37646184/dioxido-de-cloro-cds-oclo-3000>]

- “OCLO 3000 (Gotero) – Immune Booster and Antiviral
Dioxido de cloro (CDS) 3000 ppm

El dióxido de cloro en solución acuosa (CDS) es un potente agente oxigenante que potencia el sistema inmunológico además de resultar ser un antiséptico que permite eliminar un gran número de patógenos. Esta solución puede ser utilizada para combatir un gran número de infecciones virales incluyendo el COVID-19. “

“OCLO 3000 (Dropper) - Immune Booster and Antiviral
Chlorine dioxide (CDS) 3000 ppm

Chlorine dioxide in aqueous solution (CDS) is a powerful oxygenating agent that enhances the immune system as well as being an antiseptic that eliminates a large number of pathogens. This solution can be used to combat a large number of viral infections including COVID-19.”

(Translated) [from your product listing on your eCrater storefront <https://oclo.ecrater.com/p/37864511/dixido-de-cloro-cds-oclo-3000>]

- “Miles de personas se han utilizado el dióxido de cloro y se han recuperado de contagios provocados por los virus. Las autoridades sanitarias y gubernamentales demonizan este milagroso producto declarándolo como un peligroso desinfectante, confundiendo a las personas ignorantes de sus grandes beneficios. Este gas fácilmente soluble en agua en las concentraciones precisas puede combatir numerosos patógenos entre ellos, virus y otros microorganismos dañinos a la salud.” “Thousands of people have used chlorine dioxide and have recovered from virus infections. Health and government officials demonize this miraculous product by declaring it a dangerous disinfectant, confusing ignorant people of its great benefits. This gas easily soluble in water at precise concentrations can combat numerous pathogens including viruses and other health-damaging microorganisms.” (Translated) This post provides a link to your webpage <https://dioxidodecloro.us> [from a November 17, 2020 post on your Facebook social media webpage <https://facebook.com/Hallandale.Beach.2018/>]

Some examples of the previous claims on your websites that established the intended use of your products and misleadingly represented them as safe and/or effective for the treatment or prevention of COVID-19 included:

- “B117...New variant of coronavirus, the most contagious and dangerous in the United States [,] Rescuing Chlorine Dioxide and its great curative potential against pathogens . . . OCLO Nanotechnology Science manufactures different products with chlorine dioxide in aqueous CDS solution, in order to combat numerous viruses and other pathogens, according to protocols established by the German scientist Dr. Andreas Kalcker as a result of his scientific research and extensive experience of (sic)-practices. human clinics.” [from your webpage <https://dioxidodecloro.us>, accessed April 15, 2021]
- “Scientific Results - Efficacy of Chlorine Dioxide
Journal of Molecular Genetics Published March 8, 2021
Determinación de la eficacia del dióxido de cloro en el tratamiento de COVID 19
Conclusion: El dióxido de cloro es eficaz en el tratamiento del COVID19 y en este trabajo se proponen los mecanismos de acción por los que actúa para conseguirlo”
“Determination of the efficacy of chlorine dioxide in the treatment of COVID 19
Conclusion: The chlorine dioxide is effective for the COVID19 treatment and this work proposes the mechanisms of action to achieve it.” (Translated) [from your webpage <https://dioxidodecloro.us>, accessed April 15, 2021]
- “Antiviral efectivo . . .
El dióxido de cloro en su forma inicial como Mineral Miracle Solution (MMS) ha sido utilizado ampliamente y con una extraordinaria eficacia contra el virus de la malaria, que azota fuertemente algunos países del África. Recientemente fue permitido por las autoridades Bolivianas para ser utilizado en una gran parte de su población durante la pandemia del COVID-19, salvando numerosas vidas humanas . . .”
“Effective Antiviral . . .
The chlorine dioxide in its original form as Mineral Miracle Solution (MMS) has been used widely and with extraordinary efficacy against the malaria virus....and recently was permitted by the Bolivian authorities to be used in most of the country population during the COVID-19 pandemic, saving numerous human lives . . .” (Translated) [from your webpage <https://dioxidodecloro.us>, accessed April 15, 2021]
- “Strong cellular oxygenating agent, could be used as an antiviral, antibacterial, in general disinfection, body detoxification killing pathogens and elimination of heavy metals. Add 15-20 drops to a glass of drinking water to prepare CSD 50 ppm” [from an image of your product label on your webpage <https://dioxidodecloro.us/products/oclo-3000-dioxido-de-cloro-oral-gotas>, accessed April 15, 2021]
- “Chlorine dioxide in aqueous solution (CDS) is a powerful oxygenating agent that enhances the immune system as well as being an antiseptic that eliminates a large number of pathogens. This solution can be used to combat a large number of viral infections including COVID-19 . . .

Add 15 to 20 drops of the CDS solution to HALF GLASS of drinking water (120 mL) to obtain a solution of 25 to 30 ppm, a concentration indicated for human consumption safely.” [from your webpage <https://dioxidodecloro.us/products/oclo-3000-dioxido-de-cloro-oral-gotas>, accessed April 15, 2021]

We note that, as of the date of this letter, your internet website <https://dioxidodecloro.us> has been removed. Due to the serious public health concerns related to the marketing and sale of unapproved drugs for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, it is essential that these violations do not recur.

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 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 address these violations. Include an explanation of each step being taken to prevent the recurrence of any 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 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 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 the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

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 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 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. 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 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 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
Associate Director
Division of Advertising Practices
Federal Trade Commission