U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

Date: March 5, 2021

TO: IoWipe2020@gmail.com – Elise and Max Rivers, CAMA Wellness Center
6782 Germantown Ave.
Philadelphia, PA 19119

IodoRios, LLC
500 Telner Street
Philadelphia, PA 19118

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.cp.camacenter.com on February 8, 2021, and March 2, 2021, respectively. We also reviewed your social media website at www.facebook.com/IoWipe, where you direct consumers to your website http://www.cp.camacenter.com/, to purchase your products[1]. The FDA has observed that your website offers a hand wipe product for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] in people. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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.[3] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[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

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[1] Your social media website at www.facebook.com/IoWipe also directs consumers to www.iowipe.com which automatically redirects to your website http://www.cp.camacenter.com/.

[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 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/.

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 websites and/or labeling that establish the intended use of your product and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19 include:

- On a package insert that accompanies your product, under "WHEN SHOULD I REPLACE MY WIPE":
    - "However due to COVID-19 being a readily communicable disease, to be safe, we'd like you to replace it when it starts to fade from jet black or have any discoloration. This would be a sign that its iodine, the active ingredient, is beginning to be depleted (and why we say "You can see it working!). We are recommending this more conservative measure for the time being, while we pursue COVID-19 specific testing. Bear in mind that COVID-19 is an extremely easy virus to destroy outside the body, and the wipe has been tested on much tougher bugs."

- "A Chestnut Hill family is producing a sanitizing wipe that lasts 30 days and can be used 600 times . . . Even at nearly 91 years old, inventor Solomon Rosenblatt is still figuring out new ways to wipe away bacteria, fungi, and viruses. His latest product is especially relevant during COVID-19. IoWipe is a reusable, iodine-based sponge that can be used to wipe hands." [from your webpage www.cp.camacenter.com/iomedia, you also posted this with a parenthetical "(available at IoWipe.com)" on a September 2, 2020 post on your Social Media webpage https://www.facebook.com/IoWipe/]

- "Hill scientist, 90, invents 'IoWipe'; combats pandemic . . . Though the invention was created years ago, an intensive need for it didn't seem to exist until the COVID-19 global pandemic. The product came into existence in late 2019, just before the need materialized . . . 'There is a definite need now for IoWipe in light of the global pandemic and future pandemics, which are likely to occur more frequently. It is a personal, convenient, reusable, cost-effective wipe that releases iodine in safe amounts. I believe it is a superior option, as compared to alcohol gels and disposable wipes.'" [from your webpage www.cp.camacenter.com/iomedia]

- "After sending out our COVID-19 email about temporarily closing CAMA, our acupuncture center to our patients with a mention about IoWipes, our anti-viral wipes, we ended up with 30 orders, many of them local. So tonight we are driving around delivering anti-viral hand wipes and cell phone wipes in party bags two [*sic*] friends and patients!" You also replied to your post with "IoWipes - Reusable Hand Wipes available at iowipe.com [from a March 24, 2020 post on your Social Media webpage https://www.facebook.com/IoWipe/]

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 product identified above. Thus, any coronavirus-related prevention 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. 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. 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 -S

Digitally signed by Donald D. Ashley -S
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Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

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Date: 2021.03.05 08:48:27 -05'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission