WARNING LETTER

Iotech International, LLC

MARCS-CMS 617715 — MARCH 15, 2022

Product:

Drugs

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Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Federal Trade Commission (Federal Trade Commission)

WARNING LETTER

DATE: March 15, 2022

Unapproved New Drug 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.iotechinternational.com on July 30 and September 9, 2021; and March 9, 2022, respectively. We have also reviewed your Facebook and Instagram social media website at the Internet addresses, https://www.facebook.com/iotechintl/ and https://www.instagram.com/iotech.international/, respectively, where you direct consumers to your website, www.iotechinternational.com, to purchase your products.

The FDA has observed that your website offers “ioRinse” (also referred to as “ioRinse™ RTU”) and “ioCleanse Molecular iodine Hand Cleanser” for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] 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(ee) of the FD&C Act, 21

U.S.C. § 352 (ee). The introduction or delivery for introduction of such 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.[2] 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.[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 any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Examples of the claims observed on the "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" product labeling that provide evidence of the intended uses (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:

• "A New Super Class of Anti-microbials that kill #coronavirus . . . @iotech.international developed novel Anti-microbials that kill #coronavirus and surpass Chlorihexidine Gluconate in Efficacy. Safe . . . Highly engineered products created by a dentist and chemists. Order today: @iotech.international" [from a March 10, 2020 post on your Instagram webpage, https://www.instagram.com/iotech.international/]

• "The aim of the present study was to evaluate and compare the efficacy and cytotoxicity of four different mouthwashes containing 1.5% hydrogen peroxide, 0.2% povidone, 0.12% chlorhexidine and 100 ppm molecular iodine for the ability to inactivate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) . . . **Conclusion:** The spread of infection through aerosol and splatter has long been considered one of the main concerns in the dental community. A preprocedural rinse with 100 ppm molecular iodine will play a vital role in combating COVID-19 pandemic by preventing the spread of infection." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products]

• "Iotech International's formula 100-S [containing molecular iodine] displayed the greatest antiviral activity of all the tested rinses, completely inactivating SARS-COV-2 within 30 seconds." [from an article entitled "Comparative Analysis of Antiviral Efficacy of Four Different Mouthwashes against Severe Acute Respiratory Syndrome Coronavirus 2: An In Vitro Study" that you provide a link to on your website and that accompanies your products]

• "Introducing ioCleanse . . . Non-Staining IoCleanse Hand Cleanser contains the most powerful form of iodine, Molecular Iodine . . . Successfully tested to destroy normal Coronavirus (strain #229E) within seconds. . . . Clinically Proven: Iodine is more effective as an ANTIVIRAL AGENT than Alcohol Sanitizers" [from an April 18, 2020 post on your Facebook webpage, https://www.facebook.com/iotechintl/]

Based on the above claims, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" 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, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" are intended for use as an oral antiseptic rinse and as a consumer topical antiseptic, respectively.

This oral antiseptic rinse and topical antiseptic 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 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 "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" 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).[4]

We note that over-the-counter (OTC) topical antiseptic products, like "ioCleanse Molecular iodine Hand Cleanser," had been the subject of rulemaking under the Agency's OTC Drug Review. In particular, such products 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 like "ioRinse" were addressed in a 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). The Oral Antiseptics Proposed Rule classified a number of active ingredients, including iodine, as Category III for use by consumers in antiseptic-containing drug products applied topically to the oral cavity to help prevent infection in minor cuts, scrapes or oral irritation caused by dental procedures, dentures, orthodontic appliances, or accidental injury, because additional effectiveness data are needed to support a determination that a drug product containing one of these active ingredients would be GRASE for use as an OTC oral antiseptic (59 FR 6084 at 6121-6122).

Section 505G of the FD&C Act addresses 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 and comply with all other applicable requirements.

However, your "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products do not conform to the 1994 TFM, the Oral Antiseptics Proposed Rule, or 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.

Specifically, your labeling claims[5] suggesting that your oral antiseptic rinse and topical antiseptic products are effective in inactivating and thus preventing infection or disease from the novel coronavirus that causes COVID-19 go beyond merely describing the general intended uses of an antiseptic as set forth in the Oral Antiseptic Proposed Rule and the 1994 TFM, as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule, respectively.[6]

In addition, your "ioCleanse Molecular iodine Hand Cleanser" product contains an active ingredient, molecular iodine, which was not one of the three active ingredients classified as Category III in the 1994 TFM. Although molecular iodine is not explicitly identified as an active ingredient on the label of your "ioCleanse Molecular iodine Hand Cleanser" products, your label and labeling clearly represent molecular iodine as an active ingredient, which is defined as a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body (see 21 CFR 201.66(b)(2)). Your labeling includes statements such as, "ioTECH International is the leading molecular iodine research and manufacturing company dispensing a patented, breakthrough germicidal product line branded as ioRinse and ioCleanse."

In addition, "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" products 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 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 (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 FDA, the published list will be

updated to indicate that your firm has taken such corrective actions. 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 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**.

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,

/S/

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

Sincerely,

/S/

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc:
jgolden@goldendentalsolutions.com
Curt Lawler, Goldendent LLC
27115 Gratiot Ave. Ste B
Roseville, MI 48066

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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 (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/ (https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

4 We note that "ioRinse" and "ioCleanse Molecular iodine Hand Cleanser" 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.

5 The FD&C Act defines labeling in broad terms, such that labeling means all labels and "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article (see section 201(m) of the FD&C Act (21 U.S.C. 321(m)). This definition does not require labeling to be physically attached to a drug product.

6 The 1994 TFM covers health care antiseptics that are indicated for use to help reduce bacteria that potentially can cause disease and health care and consumer antiseptics that are indicated for use to decrease bacteria on the skin. 59 FR at 31443.

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