WARNING LETTER

DATE:

TO: herbmoskowitz@iotechinternational.com

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Unapproved

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

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 nonprescrih2ol.Sq€.hžnpÁl'1ìp7ÓÁÐTÈAȅu§
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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 et TJ0 Tc 34.2 (e69Td(-)Tj0.001 Tc [(19, n)7 (i)-o)

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