

Serena Viswanathan Associate Director Division of Advertising Practices United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

April 30, 2021

WARNING LETTER

VIA EMAIL TO info@todosmedical.com

Gerald Commissiong Todos Medical USA 45 Wall Street New York, NY 10005

Todos Medical Ltd. 1 Hamada Street Rehovot 7670301, Israel

Re: Unsubstantiated claims for Coronavirus prevention or treatment

Dear Mr. Commissiong:

This is to advise you that FTC staff has reviewed your website at <u>https://todosmedical.com</u> in April 2021. We also reviewed your social media websites at <u>https://www.facebook.com/todosmedical/, https://twitter.com/todosmedical,</u> and <u>https://twitter.com/G_Commish</u>, where you promote a supplement you sell through your partner The Alchemist's Kitchen in its stores and at <u>https://www.thealchemistskitchen.com</u>. We have determined that you are unlawfully advertising that Tollovid prevents or treats Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or treatment claims include:

• In a press release on your website dated March 11, 2021 tiled "Todos Medical Applauds Senate and House Passage of the American Recovery Act," you state:

"Todos Medical, Ltd. (OTCQB: TOMDF), an *in vitro* diagnostics company focused on distributing comprehensive solutions for COVID-19 screening, diagnosis and immune support, as well as developing blood tests for early detection of cancer

and Alzheimer's disease, today applauded the Senate and House's passage of the American Recovery Act....

The American Recovery Act also intends to boost funding for antiviral solutions that could complement the national vaccination plan. Pfizer is currently evaluating the safety and efficacy of the injectable 3CL protease inhibitor PF-00835321 in COVID-19 patients []. The 3CL protease is a novel therapeutic target whose inhibition has been shown to dramatically slow the replication of coronaviruses in vitro in published studies [].

Todos is currently marketing the orally available 3CL protease inhibitor Tollovid[™] via The Alchemist's Kitchen in New York City, and intends to launch its own Todos branded Tollovid product direct to consumers in the United States. Tollovid is a dietary supplement that has received a Certificate of Free Sale from the US FDA and whose active ingredient is a plant extract that is tested for 3CL protease inhibition prior to final product formulation. Todos is currently marketing Tollovid as an immune boosting product that helps to support and maintain healthy immune function. There are currently no ongoing clinical trials of Tollovid, and Todos is not making any COVID-19 treatment claims for Tollovid.

Todos Medical recently trademarked Tollovir[™], its high dose version of Tollovid, and is advancing Tollovir through a randomized, double-blind, placebo controlled clinical development pathway in hospitalized COVID-19 patients in Israel with partner NLC Pharma. Todos intends to pursue a traditional therapeutic regulatory pathway for Tollovir in order to be able to make treatment claims in COVID-19."

[https://investor.todosmedical.com/news-events/press-releases/detail/104/todos-medical-applauds-senate-and-house-passage-of-the]

• In a press release on your website dated December 7, 2020 titled "Todos Medical Announces Commercial Launch of Proprietary 3CL Protease Inhibitor Dietary Supplement Tollovid[™] at The Alchemist's Kitchen" you state:

"Todos Medical (OTCQB: TOMDF), an *in vitro* diagnostics company focused on distributing comprehensive solutions for COVID-19 screening and diagnosis, and developing blood tests for early detection of cancer and Alzheimer's disease, today announced the commercial launch of its proprietary 3CL protease inhibitor dietary supplement Tollovid[™] at The Alchemist's Kitchen in SoHo district in Manhattan, New York. Tollovid, a mix of botanical extracts, is being targeted to support healthy immune function against circulating coronaviruses. Tollovid's mechanism of action is to inhibit the activity of the 3CL protease, a key protease required for the intracellular replication of coronaviruses. Tollovid was granted a Certificate of Free

Sale by the US Food & Drug Administration in August 2020, allowing its commercial sale anywhere in the United States.

Todos recently announced positive in vitro data from its joint venture partner NLC Pharma demonstrating Tollovid's potency in inhibiting the 3CL protease, as well as significant positive feedback from over 1,000 clients in Israel who have purchased Tollovid for use against circulating coronaviruses.

Mr. Lou Sagar, CEO of The Alchemist's Kitchen, said while commenting on the commercial launch of Tollovid, 'We have spent the last several months looking for new products that could assist our customers in boosting healthy immune function in the face of circulating coronaviruses. We believe that Tollovid certainly has a very attractive profile that, in combination with standard immune boosting dietary supplements such as vitamin C and vitamin D, may add a layer of protection in the event an individual has been recently exposed or is suffering from an actively circulating coronaviruses, and we feel comfortable that Tollovid may be helpful for our community as we head into what some public health officials have described as the worst public health crisis in our nation's history.'

For further information on commercial availability of Tollovid, please contact The Alchemist's Kitchen at (518) 625-3477 or email herbalist@thealchemistskitchen.com."

[https://investor.todosmedical.com/news-events/press-releases/detail/100/todos-medicalannounces-commercial-launch-of-proprietary]

• In a press release on your website dated November 20, 2020 titled "Todos Medical Announces Positive In Vitro Data for TollovidTM Confirming 3CL Protease Inhibition Mechanism of Action," you state:

"Todos Medical... today announced positive in vitro data by its joint venture partner NLC Pharma for the Company's dietary supplement Tollovid[™], demonstrating its ability to inhibit the 3CL protease. The 3CL protease is an enzyme that is required for the intracellular replication of coronaviruses. Tollovid received a certificate of free sale from the FDA in August 2020 and is being launched commercially into the US market initially at botanical wellness store The Alchemist's Kitchen[™] in New York City....

Since the beginning of 2020, over 1,000 patients suffering from diseases caused by circulating coronaviruses in Israel have received various dosing regimens of Tollovid, including both hospitalized and non-hospitalized patients. There has been overwhelmingly positive customer feedback on their experience with the product,

including significant positive feedback from physicians. Based on the results of this market research study conducted in Israel, as well as the pioneering research advanced by Dr. Dorit Arad on the entire coronavirus family of viruses for over the last 20 years, NLC Pharma is preparing to initiate a randomized clinical trial in Israel in December 2020 to evaluate the potential for Tollovid to treat patients suffering from actively circulating coronaviruses."

[https://investor.todosmedical.com/news-events/press-releases/detail/96/todos-medical-announces-positive-in-vitro-data-for]

- In a press release on your website dated October 29, 2020 titled "Todos Medical Trademarks Tollovid for Dietary Supplement NLC-001 and Enters Into Private Label & Distribution Agreement With The Alchemists [sic] Kitchen" you state:
 - "Tollovid is a proprietary blend of plant extracts administered orally as dietary supplement
 - The US FDA granted a Certificate of Free Sale for Tollovid on August 28, 2020
 - Tollovid ingredients inhibit the 3CL protease, a key protease required for coronavirus replication
 - o The Alchemist's Kitchen will launch Tollovid in November 2020 . . .

Tollovid is an orally administered proprietary blend of plant extracts that includes a powerful 3CL protease inhibitor that helps support and maintain healthy immune function. The 3CL protease plays a vital role in the intracellular replication of coronaviruses, and 3CL protease inhibition is being evaluated as a potential therapeutic target for COVID-19 by several groups, including Pfizer.

Concurrent with this announcement, the Company announced that it has entered into a private label and distribution agreement with The Alchemist's Kitchen, based in the SoHo district of New York City with a significant online presence.... The Alchemist's Kitchen will sell Tollovid under its Plant AlchemyTM brand and will train its herbalists to help educate consumers on how adding Tollovid to their immune boosting strategy could potentially lead to improved outcomes in the face of circulating coronaviruses...

'We are excited to have selected the brand name Tollovid[™]... and to be partnering with The Alchemist's Kitchen to bring this important immune-boosting dietary supplement into the marketplace at this critical time in the United States,' said Gerald E. Commissiong, President & CEO of Todos Medical. 'Some of the most promising data in the scientific literature to date in combatting coronaviruses has been generated by dietary supplements that help reinforce the body's ability to respond to potential challenges from a coronavirus infection. We are targeting Tollovid to be

added to this immune-boosting paradigm, and believe Tollovid could be an important part of an immune boosting strategy to help support and maintain a healthy immune system during this upcoming period of significant concern about potential circulating viruses heading into the colder weather months ahead.'..."

[https://investor.todosmedical.com/news-events/press-releases/detail/91/todos-medical-trademarks-tollovid-for-dietary-supplement]

• In a Facebook post on March 29, 2021, you state:

"ICYMI Todos President and CEO Gerald Commissiong joined Cindy Drukier on The Nation Speaks to discuss COVID-19 vaccine passports, how individuals react differently to the vaccine and the importance of immune-boosting supplements. <u>https://bit.ly/3rxdLa8</u>."

The linked page includes a video in which Gerald Commissiong is interviewed about COVID-19 vaccine passports and states: "The reason why people who are older are more prone to getting sick is because they have a lower immune response... Obviously as these variants begin to take hold, it's going to change how we look at immunity. There's obviously a lot of concern about some of these variants, especially ones that been shown to have a greater ability to overcome vaccines... One of the reasons why we chose to get into this space of immunity is because that can't be the only solution for us on an individual basis to protect ourselves.... [W]e're trying to build our immunity. We found a dietary supplement that we feel has the really strong potential to further protect people, especially with circulating coronaviruses, and so adding these immune-boosting types of supplements to your regimen is something that you can do for yourself to help protect you to the extent possible."

A Twitter post on March 29, 2021 contains a link to the same page and substantially similar text.

[March 29, 2021 Facebook post at <u>https://www.facebook.com/todosmedical/</u>, sharing shortened URL that links to <u>https://www.ntd.com/the-nation-speaks-march-27-vaccine-passport-rabbit-hole-hospitals-slow-walk-new-pricing-rules-the-day-president-reagan-was-shot_587863.html;</u> March 29, 2021 Twitter post at <u>https://twitter.com/todosmedical</u>, which was retweeted at <u>https://twitter.com/G_Commish</u>]

In Facebook and Twitter posts on December 8, 2020, you state: "Our proprietary 3CL protease inhibitor dietary supplement Tollovid[™] is being targeted to support healthy immune function against circulating coronaviruses. Tollovid is now available at The Alchemist's Kitchen: [links to Alchemist's Kitchen webpage to purchase Tollovid[™] Immune Support Capsules]."

> [December 8, 2020 posts at <u>https://www.facebook.com/todosmedical/;</u> <u>https://twitter.com/todosmedical;</u> the latter was also retweeted at <u>https://twitter.com/G_Commish</u>]

In a Facebook post on December 7, 2020, which includes an image of a Tollovid supplement bottle, you state: "Todos announced the commercial launch of its proprietary 3CL protease inhibitor dietary supplement Tollovid[™] at The Alchemist's Kitchen in SoHo district in Manhattan, New York. Tollovid, a mix of botanical extracts, is being targeted to support healthy immune function against circulating coronaviruses. Tollovid's mechanism of action is to inhibit the activity of the 3CL protease, a key protease required for the intracellular replication of coronaviruses. Tollovid was granted a Certificate of Free Sale by the US Food & Drug Administration in August 2020, allowing its commercial sale anywhere in the United States." The post links to the December 7, 2020 press release at the Todos Medical webpage described above.

[December 7, 2020 Facebook post at <u>https://www.facebook.com/todosmedical/</u>, sharing link to <u>https://investor.todosmedical.com/news-events/press-</u>releases/detail/100/todos-medical-announces-commercial-launch-of-proprietary]

• In a Twitter post on December 7, 2020, which includes an image of a Tollovid supplement bottle, you state: "See attached first picture of Tollovid bottle, being launched at The Alchemist's Kitchen in SoHo, Manhattan, NY. Key 3CL protease inhibitor dietary supplement to help mitigate intracellular replication of coronaviruses. Launch announced today..."

[December 7, 2020 Twitter post at <u>https://twitter.com/G_Commish</u>, also retweeted at <u>https://twitter.com/todosmedical</u>]

In a Facebook post on October 29, 2020 you state: "Todos today announced that it has selected the brand name 'TollovidTM' for its proprietary, patent protected 3CL protease inhibitor, previously called NLC-001. Todos licensed the exclusive worldwide distribution rights for Tollovid, excluding Israel, from Israel-based joint venture partner NLC Pharma in September 2020. Tollovid is an orally administered proprietary blend of plant extracts that includes a powerful 3CL protease inhibitor that helps support and maintain healthy immune function. The 3CL protease plays a vital role in the intracellular replication of coronaviruses, and 3CL protease inhibition is being evaluated as a potential therapeutic target for COVID-19 by several groups, including Pfizer. Learn more: https://bit.ly/3e9fVYI." The post links to the October 29, 2020 press release at the Todos Medical webpage described above.

[October 29, 2020 Facebook post at <u>https://www.facebook.com/todosmedical/</u>, sharing shortened URL that links to <u>https://investor.todosmedical.com/news-</u>

> events/press-releases/detail/91/todos-medical-trademarks-tollovid-for-dietarysupplement]

• In a Twitter post on October 29, 2020 you state: "The Alchemist's Kitchen will sell Tollovid under its Plant Alchemy brand & train its herbalists educate consumers on how adding Tollovid to their immune boosting strategy could potentially lead to improved outcomes in the face of circulating coronaviruses[.]" The post links to the October 29, 2020 press release at the Todos Medical webpage described above.

[October 29, 2020 Twitter post at <u>https://twitter.com/todosmedical</u> sharing link to <u>https://investor.todosmedical.com/news-events/press-releases/detail/91/todos-</u>medical-trademarks-tollovid-for-dietary-supplement]

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.

You are also advised to review all other claims for your products and services and immediately cease making claims that are not supported by competent and reliable scientific evidence.

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 back money to consumers.

Within 48 hours, please send a message to Richard Cleland, Assistant Director 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 Richard Cleland at 202-326-3088.

Very truly yours,

Serena Viswanathan

> Associate Director Division of Advertising Practices

cc: The Alchemist's Kitchen (119 Crosby St., New York, NY 10012) via email to info@thealchemistskitchen.com Facebook via email to consumerpolicy@fb.com Twitter via email to dc-help@twitter.com