



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION



## **WARNING LETTER**

Date: November 17, 2020

TO: [frank.jaksch@chromadex.com](mailto:frank.jaksch@chromadex.com) – Frank Jaksch, Co-Founder, Chromadex  
Robert Fried, CEO, Chromadex  
10900 Wilshire Blvd.  
Suite 600  
Los Angeles, CA 90024

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 websites at the Internet addresses [www.chromadex.com](http://www.chromadex.com) and [www.truniagen.com](http://www.truniagen.com) on various dates since September 16, 2020. We also reviewed your social media website at [www.facebook.com/Chromadex](https://www.facebook.com/Chromadex), where you direct consumers to your website [www.truniagen.com](http://www.truniagen.com) to purchase your products.<sup>1</sup> The FDA has observed that your website [www.truniagen.com](http://www.truniagen.com) offers the products Tru Niagen 300mg, Tru Niagen 150mg, and Tru Niagen Stickpacks (the “Tru Niagen products”) for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>2</sup> 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.<sup>3</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>4</sup> 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

<sup>1</sup> We also observed that your social media website [www.facebook.com/Chromadex](https://www.facebook.com/Chromadex) also directs consumers to your website [www.chromadex.com](http://www.chromadex.com), which directs consumers to your website [www.truniagen.com](http://www.truniagen.com) to purchase your products.

<sup>2</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>3</sup> Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration has been renewed for an additional 90 days three times. The most recent renewal went into effect on October 23, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. October 2, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>).

<sup>4</sup> President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Your Tru Niagen products are labeled to contain nicotinamide riboside (NR). On your websites, you claim that these products increase levels of nicotinamide adenine dinucleotide (which you abbreviate as “NAD” or “NAD+”).<sup>5</sup> Claims on your websites also suggest that depletion of NAD/NAD+ worsens COVID-19 and that increasing NAD/NAD+ levels—including through NR supplementation—is safe and/or effective for the treatment or prevention of COVID-19. Some examples of the claims on your websites 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:

On your social media website <https://www.facebook.com/ChromaDex/>:

- In an April 20, 2020 post, you state: “. . . early preclinical data suggests that increasing cytoplasmic NAD levels through a NAD precursor, such as NR, may support innate immunity to coronaviruses and other viruses.” This post links to an article titled, “ChromaDex Commits to COVID-19 Research Following Promising Initial Preclinical Findings Showing Viral Infections Deplete NAD and SARS-CoV-2-Infected Cells Activate NAD Defense Pathway That Utilizes Nicotinamide Riboside (NR)” at <https://investors.chromadex.com>.
- In a July 7, 2020 post, you state: “As COVID-19 cases continue to rise, ChromaDex seeks to be of service to public health. We are pleased to announce the initiation of a preclinical study on the effects of raising NAD+ levels on COVID-19 animal models. . . .” This post links to an article titled, “ChromaDex and the NIH-NIAID Rocky Mountain Laboratories Announce Study to Assess the Therapeutic Potential of Niagen® in COVID-19 Animal Models” at [www.businesswire.com](http://www.businesswire.com), which includes the following claim:
  - “A recent preclinical study showed SARS-CoV-2 infected cells suffer significant NAD+ depletion leading to disruption of innate anti-viral immune activity, while other preclinical data suggest that modulation of inflammasome activity in immune cells by NAD+ may be important in the severe inflammation observed in patients infected with COVID-19. ChromaDex’s Niagen is proven to effectively restore and maintain NAD+ levels.”
- In a July 9, 2020 post, you state: “‘Dr. Brenner and his colleagues’ preclinical research provides new insight into the critical role NR may play in replenishing the NAD that is depleted under viral infection,’ says ChromaDex CEO Rob Fried. ‘We will support continued research that will examine our ingredient’s potential to impact the response to viral infection.’”

This post links to an article titled, “ChromaDex Announces New Study Results Highlighting Promising Anti-Viral Effects of Niagen® in Coronavirus Cell Model” at [www.businesswire.com](http://www.businesswire.com), which includes the following claims:

- *“Dr. Charles Brenner and a team of scientists from three US universities find that Niagen® decreases Coronavirus replication in animal cells.”*

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<sup>5</sup> For example, in a July 16, 2020 post on your Facebook page, <https://www.facebook.com/ChromaDex/>, you state: “The study found that Niagen® supplementation boosted NAD+ levels . . . .” Your webpage [www.chromadex.com/tru-niagen/](http://www.chromadex.com/tru-niagen/) states: “Tru Niagen® increases your NAD, every time you take it.”

- “ChromaDex Corp. (NASDAQ:CDXC) today announced the latest preclinical findings indicating Niagen® (patented nicotinamide riboside) inhibits replication of a form of Coronavirus, the virus that causes COVID-19 infection, in mouse cells.”
- In an October 6, 2020 post, you state: “A new Phase 2 clinical study in mild-to-moderate #COVID19 patients in Turkey found a nutritional protocol including nicotinamide riboside (NR), L-serine, N-acetyl-L-cysteine (NAC), and L-carnitine tartrate plus standard of care (hydroxychloroquine) reduced #recovery time by nearly 30% to 6.6 days.”

This post links to an article titled, “ChromaDex Announces Study Results Showing Nutritional Protocol Including Nicotinamide Riboside Plus Standard of Care Reduces Recovery Time in COVID-19 Patients by Nearly 30%” at <https://investors.chromadex.com>, which includes the following claims:

- “Phase 2 study finds addition of nutritional protocol to standard of care reduces recovery time to 6.6 days from 9.3 in mild-to-moderate COVID-19 patients”
- “The Phase 2 study reported patients with mild-to-moderate COVID-19 experienced a 29% reduction in recovery time when receiving the standard of care in combination with a nutritional protocol including nicotinamide riboside (NR). The additional nutritional support . . . reduced average recovery time to 6.6 days in comparison to average placebo recovery time of 9.3 days.”
- ““This is a positive and timely clinical trial with a powerful topline result showing accelerated recovery of Turkish COVID-19 patients treated with a nutrient protocol including 2 grams of daily NR,” said Dr. Brenner [Chief Scientific Advisor at ChromaDex].”

You should take immediate action to correct 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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@fda.hhs.gov)** describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter 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 corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. 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 are subject to detention and refusal of 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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@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 or treatment 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. 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](mailto: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,

**William A.  
Correll Jr -S**

Digitally signed by  
William A. Correll Jr -S  
Date: 2020.11.16 18:45:52  
-05'00'

William A. Correll  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Sincerely,

**SERENA  
VISWANATHAN**

Digitally signed by SERENA  
VISWANATHAN  
Date: 2020.10.30 14:23:14  
-04'00'

Serena Viswanathan  
Acting Associate Director  
Division of Advertising Practices  
Federal Trade Commission