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Stale News

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A closer look at CDXC's "positive" Phase 3 trial news yesterday reveals some troubling facts.

The study, conducted in Turkey, was very narrow, focused on young people without co-morbidities, whose likelihood of rapid recovery from Covid19 is high.

Furthermore, CDXC had already touted this news in a press release on February 24.

ChromaDex **Investor Relations**

02/24/2021

New Phase 3 Clinical Study Finds Nutritional Protocol Including Nicotinamide Riboside Accelerates Recovery in Mild-to-Moderate COVID-19 Patients

The study

The Phase 3 trial that CDXC touted on Monday was conducted at a single site in Istanbul among 304 patients with a mean age of 36 and without co-morbidities.[1] The Phase 2 trial had been conducted with 93 patients. According to the FDA. A typical Phase 3 trial is for 300-3,000 subjects and is conducted over 1-4 years.[2]

The published study reports that it was supported by a grant from the Knut and Alice Wallenberg Foundation in Sweden and "in partnership with" CDXC.[3]

> The study was conducted in partnership with Stockholm-based ScandiBio Therapeutics AB and California-based ChromaDex (NASDAQ:CDXC), which provided one of the four ingredients (nicotinamide riboside) through the ChromaDex External Research Program (CERP). Together with the strategic partner Viscoran (Turkey), a submission for drug approval has been submitted to the Ministry of Health in Turkey.
>
> Funding for the research was provided by the Knut and Alice Wallenberg Foundation.

1 https://onlinelibrary.wiley.com/doi/10.1002/advs.202101222
2 https://www.fda.gov/patients/drug-development-process/step-3-clinical-research
3 https://www.kth.se/en/aktuellt/nyheter/covid-19-patients-recover-faster-with-metabolic-activator-treatment-study-shows-1.1087654

ChromaDex (CDXC)

June 29, 2021

JCAP

FDA and FTC violations

"The “good news” about the alleged effects of one of Tru Niagen's components on Covid19 could get CDXC into more hot water with the U.S. government. CDXC has already been cautioned by the Food and Drug Administration and the Federal Trade Commission in relation to promotional statements. The agencies issued warning letters in November 2020 and April 2021 instructing CDXC to stop telling the public that Tru Niagen has benefits for fighting Covid.

The November 17, 2020 letter from the FDA said:

> 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).[4]

The letter went on to criticize CDXC for claiming without basis that:

> 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+”).[5] 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.

The FDA gave CDXC 48 hours to remove the promotional statements. Yet CDXC received another warning letter in April. The contents of this letter have not been disclosed. But the FDA told CDXC that it would update its website as soon as CDXC addressed the problem. The website as of June 28 had not been updated.

Fraudulent Coronavirus Disease 2019 (COVID-19) Products

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The U.S. Food and Drug Administration is issuing **warning letters** to firms for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure coronavirus disease 2019 (COVID-19). We are actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unapproved products and making false or misleading claims, including, by pursuing warning letters, seizures, injunctions or criminal prosecutions against products and firms or individuals that violate the law.

Content current as of: 06/23/2021

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.

Date Issued	Firm Name	Product Name and Image[1]	Corrective Status
11/17/2020	ChromaDex	"Tru Niagen products"	

4 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/chromadex-607692-11172020

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