



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



WARNING LETTER

Date: February 25, 2021

TO: questions@drfitt.com – Christy McCord
PYRLess Group, LLC dba Dr. Fitt
812 S Georgia St
Amarillo, TX 79106

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 <https://drfitt.com> and <https://drfittinfo.com> on various dates since February 3, 2021, and February 10, 2021, respectively. We also reviewed your social media websites at <https://www.facebook.com/dfitt/>, <https://www.facebook.com/roby.mitchell>,¹ and <https://www.facebook.com/IntelligentDesignAmarillo/>, where you direct consumers to your website <https://drfitt.com> to purchase your products. The FDA has observed that your website offers the products Buffered C Powder, Get Well 2 Day Vit A, Get Well 2 Day Vit D3, Robynzyme, and OMG Cell Protek for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19² 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.³ In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.⁴ 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

¹ In a February 1, 2021 post on <https://www.facebook.com/roby.mitchell>, you state: “Dr. Mitchell is the founder of PYRLess Group, LLC, which holds the legal rights to the use of Dr. Mitchell’s name, voice, and likeness, including all applicable rights of publicity, as well as his logo, copyrighted materials and trademarks. . . . The name, voice, and likeness, including all applicable rights of publicity, of Roby Mitchell belong to PYRLess.”

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

³ 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>.

⁴ 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/>.

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.

Your website <https://drfitt.com> states that your Buffered C Powder contains vitamin C, your Get Well 2 Day Vit A contains vitamin A, your Get Well 2 Day Vit D3 contains vitamin D3, your OMG Cell Protek contains iodine and iodide, and your Robynzyme “combines hydrochloric acid with digestive enzymes and B vitamins.” 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:

- “Iodine is also a halogen. It also kills bacteria, viruses and fungi at a 99.9% kill rate . . . In this role, iodine functions like chlorine in a swimming pool, a disinfectant against bacteria, viruses like COVID-19 and fungi. . . . Ideally, everyone should be supplementing with an iodine supplement like our Cell Protek (3/day for adults. 1/day for children). However, we used nebulized iodine (SSKI) and dilute hydrchloric [sic] acid (another source of the chlorine molecule) to treat upper respiratory infections and never needed to give patients standard antibiotics. Iodine is a safe, highly effective, inexpensive treatment for COVID-19, other viruses, bacteria and fungi. . . . Iodine is part of the Passover Protocol. . . . Seems to [sic] simple, huh? That this pandemic could have been thwarted with iodine, vitamin D, vitamin C and vitamin A.” [from an August 7, 2020 post on your Facebook social media website <https://www.facebook.com/DrFitt/>]
- “Q: I work in a medical facility, we are required to get the flu shot or we do not work. I have your Vitamin A and D drops. Please refresh my memory on when to take them to combat the flu shot. Also, will this work if we are required to get the Covid vaccination when it is available? . . .

Dr Fitt: Two days before getting either shot, follow directions on labels. This will give you 400,000 iu of vitamin A/day for 2 days. And 50,000 iu of vitamin D/day for 2 days.

Vitamin A is actually a hormone that stimulates the production of proteins called cytokeratins. Cytokeratins form a protective barrier around cells that prevents viruses from entering cells. If viruses can't enter cells, they can't multiply. If they can't multiply, they can't stimulate the immune system response that causes flu symptoms, including death. . . .

Vitamin D is also a hormone. It stimulates the production of proteins called cathelicidins. Cathelicidins are the ‘bullets’ immune cells use to kill viruses, bacteria and fungi. If vitamin D levels are low, it's like sending soldiers into battle with no bullets. The primary deciding factor in who got sick from COVID-19 was the levels of vitamin D. Keep your vitamin D levels at 70 or above and you won't get viral infections. . . .

Download the Passover Protocol. Regardless of COVID-19, you should maintain an internal environment that prevents critter overgrowth. . . . You prevent not only viral infections but all the above conditions if you adopt the Passover Protocol.” [from a September 8, 2020 post on your Facebook social media website <https://www.facebook.com/roby.mitchell> in which you also provide a link to your website <http://drfittinfo.com/passover-protocol/>]

- “Persistent COVID symptoms? . . . Sooooo, one obvious strategy is similar to that employed when an active shooter is detected in the building. You institute a lockdown to prevent the shooter from entering other entry ways. With viruses, this is done by ramping up levels of vitamin A. . . . Vitamin A= Lockdown. The ‘lockdown’ can be initiated with 400,000 iu of vitamin A palmitate (Not beta carotene) each day for 2 days. . . .

Once lockdown is in place, we need to take out the shooter. Several ways to do that. Vitamin C is a potent and proven virucidal that kills viruses on contact. . . . Added benefit of vitamin C is that it also strengthens cell membranes to prevent viruses from infecting new cells. . . . Iodine is in the class of chemicals called halogens. . . . Halogens are potent, broad spectrum antimicrobials. . . . Vitamin D3 stands out as the most weapon against respiratory viruses.” [from an October 20, 2020 post on your Facebook social media website <https://www.facebook.com/DrFitt/>]

- “I’m breathing the same air as the people who get COVID and die. Yet, I had a patient who tested positive cough into my water several times and swabbed his nasal passage and transferred it to mine. I didn’t get even a sniffle because I follow the Passover Protocol. Part of the Passover Protocol can be used as treatment. . . . Pick up Get Well 2 Day protocol. Follow instructions on labels for 2 days. Get powdered vitamin C and one tsp each hour while awake. This protocol does 3 things. The vitamin A puts deadbolt on to prevent viruses from entering new cells. . . . The vitamin D loads your foot soldiers (T cells and macrophages) with ammo called cathelicidins. Cathelicidins destroy viruses like Raid destroys roaches. Vitamin is also virucidal-kills viruses on contact. Vitamin C also plays ‘deadbolt’ in that it makes your cell membranes stronger and harder to penetrate.” [from an October 20, 2020 post on your Facebook social media websites <https://www.facebook.com/DrFitt/> and <https://www.facebook.com/IntelligentDesignAmarillo/>]
- “There is one simple, effective, inexpensive way to stop Covid infections in 2 days. That is the Get Well 2 Day protocol.” [from an October 21, 2020 post on your Facebook social media websites <https://www.facebook.com/DrFitt/> and <https://www.facebook.com/roby.mitchell/>]
- “Passover Protocol . . . This information should change the narrative to one focused on preventing the increase in the number of viruses to a tipping point that causes the cytokine storm. It is fairly simple: . . .

Vitamin A deadbolts cell membranes such that viruses cannot get inside and make millions of copies. . . . If you do get a viral infection, 400,000 iu per day of vitamin A per day (not beta carotene) for two days will abort the infection, as it will strengthen cell membranes, preventing more cells from becoming breeding centers for new viruses. . . .

Get adequate vitamin D. Cholecalciferol is actually a hormone that stimulates your cell DNA to produce a variety of proteins. One class, cathelicidins, are your internal antimicrobials. If viruses are locked outside the cell due to adequate vitamin A, they get destroyed by cathelicidins. Less sun exposure in the Fall sets you up for low vitamin D and more viral infections, including flu viruses. . . .

Be sure there is plenty of hydrochloric acid in your gut. I call HCl the “Passover” molecule. As in the Bible story, a pestilence that affects some will ‘passover’ people who have adequate hydrochloric acid. Children are often born not producing adequate hydrochloric acid. The elderly have senescent production. This is why these two populations are more vulnerable to infections and targeted with vaccines. . . .

Vitamin C. Ascorbic acid, like cathelicidins, is virucidal – it kills viruses on contact. . . . In case you do get a viral infection, use the “vitamin C/bowel tolerance” protocol.

Iodine/iodide – these mineral moieties have the same effect in your bloodstream as chlorine does in a swimming pool or municipal water. Minerals in this class called ‘halogens’ are potent critter killers.” [from your webpage <https://drfittinfo.com/passover-protocol/>]

- “Get Well 2 Day Vitamin A was formulated with the ‘Get Well 2 Day Protocol’ (recommended Dr. Fitt for abatement of viral infections) in mind.” [from your webpage <https://drfitt.com/get-well-2-day-vit-a/>]
- “Get Well 2 Day Vitamin D3 was formulated with the ‘Get Well 2 Day Protocol’ (recommended Dr. Fitt for abatement of viral infections) in mind.” [from your webpage <https://drfitt.com/get-well-2-day-vit-d3/>]
- “Vitamin C also has anti-viral properties that make it a good supplement to keep Winter viruses at bay.” [from your webpage <https://drfitt.com/buffered-c-powder/>]
- “Halogens are powerful antimicrobials that kill bacteria, viruses and fungi. . . . Iodine is also a halogen. It has a long history as a topical and oral antiseptic. . . . Taken orally, iodine and it’s mineral moiety iodide do in your body what chlorine does in a swimming pool- prevents overgrowth of bacteria, viruses and fungi. . . . Thanks to the work of iodine pioneers like gynecologist Guy Abraham M. D., we now know that all six trillion of your human cells need antimicrobial protection from either iodine or iodide.” [from your webpage <https://drfitt.com/omg-cell-protek/>]
- From a July 26, 2020 YouTube video titled “Intelligent Design against COVID-19,” which was posted under the username “Roby MitchellMD” on the website <https://www.youtube.com/watch?v=JWE8wf4fZKo&t=1s>:

“. . . things that we’re going to talk about is mechanisms that protect against all viruses not just COVID, right? [9:35-9:45]

. . . One of those mechanisms I’m talking about which is Vitamin D. . . . one of the proteins vitamin D codes for is called cathelicidins . . . when cathelicidins hit viruses, I mean they’re dead [10:25-11:05]

. . . The other thing we should have in us in order to fight off these viruses, is called vitamin A [11:50-12:05]

. . . vitamin A will stimulate the production of cytokeratins and they will build a barrier around your cells such that the virus can’t get in . . . So those two primary things, right, your level of vitamin D and your level of vitamin A are really critical on a daily basis . . . another one is your level of vitamin C . . . Vitamin C also directly virucidal [12:45-13:30]

. . . Here at age 63, doing this type of medicine as long as I have, I just learned about how important vitamin D is in preventing respiratory infections . . . [28:10-28:25]”

“Roby MitchellMD” responded to questions in the comments section of the video:

- Q: “One other question I had was how much vitamin D should we be taking daily to prevent covid from getting severe?”
A: “Enough to get blood levels up to 70-100.”
- Q: “Hey Dr. Mitchell, I didnt catch what you suggest/recommend for prophylaxis for covid 19? . . .”
A: “Vitamin D is most important. Get levels checked to make sure you’re at 70-100.”
- A: “. . . If vitamin D levels are above 70, viruses don’t survive.”

Furthermore, an Online Advisory Letter was issued to Dr. Fitt Intelligent Designs, LLC on November 7, 2018 for violations regarding products sold on your websites www.drfitt.com, www.drfittinfo.com, <https://www.facebook.com/DrFitt> and <https://www.facebook.com/IntelligentDesignAmarillo>. Various

claims and statements made on your websites and/or in other labeling showed that these products were intended for the treatment, cure, mitigation, or prevention of diseases including Alzheimer's disease, cancer, and influenza. The letter was posted here, <https://www.fda.gov/consumers/health-fraud-scams/dr-fitt-intelligent-designs-llc>. Based on our recent review, your websites continue to demonstrate that your products are intended to treat, cure, mitigate, or prevent such diseases.

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-CFSAN@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>. 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 the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

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-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. 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. 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 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
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA
VISWANATHAN
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

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