



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



WARNING LETTER

Date: February 18, 2021

TO: info@safalab.com
laura@safalab.com

Dr. Bradford Weeks, SafaLab, Inc.
317 Cascade Ave. Langley, WA 98260

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.safalab.com and www.weeksmd.com on February 8, 2021. The FDA has observed that your website www.safalab.com offers the product The Prevention 12 Pak—which you also refer to as the Coronavirus Prevention 12 Pak, and which consists of the products SOUL, CORE, Cellular Detox, Turb-O2, Vitamin C (Anti-Oxidant Assist), Vitamin D3 (Light Assist), Glutathione, Selenium, Zinc, Vitamin A, Melatonin, and Iod Assist (Iodine)—for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19¹ in people. In addition, your website www.weeksmd.com directs consumers to www.safalab.com to purchase The Prevention 12 Pak. Based on our review, this product is an unapproved new drug 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, this product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of this product 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.² In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.³ 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 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.

Some examples of the claims on your websites that establish the intended use of The Prevention 12 Pak and misleadingly represent it as safe and/or effective for the treatment or prevention of COVID-19

¹ As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

² 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>.

³ 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/>.

include:

On your website www.safalab.com/product/the-prevention-12-pak:

- “The Prevention 12 PAK –

We are all worried about the spread of the Coronavirus (COVID-19) which kills vulnerable people by Acute Respiratory Distress Syndrome (ARDS). The WHO and FDA claim that there is no cure and no prevention. Integrative medical doctors and their informed patients disagree. Here is the essential 12 Pak to buy for each of your family members and loved ones. To learn the scientific and clinical rationale for each of these essential parts of the Prevention 12 Pak, click [HERE](#) to read this article by Bradford S. Weeks, M.D.”

The words “read this article by Bradford S. Weeks, M.D.” hyperlink to your post titled “COVID-19 – how to protect yourself” at www.weeksmd.com/2020/02/coronavirus-how-to-protect-yourself/, which includes the following claims:

- “Here are the Coronavirus 12 Pak items which you can bet your life on.
 - 1) SOUL – anti-inflammatory ...
 - 2) CORE . . .
 - 3) AntiOxidant™ Assist – Vitamin C . . .
 - 4) Cellular Detox . . .
 - 5) Turb-O2™ . . .
 - 6) Melatonin – ... anti-viral ...
 - 7) Acetylglutathione . . .
 - 8) Light Assist™ – Vit D3 . . .
 - 9) Selenium – powerful anti-viral ...
 - 10) Iodine – powerful anti-pathogen ...
 - 11) Zinc – membrane protector and anti-viral agent and potentiator of anti-viral drugs ...
 - 12) A-25 (Vitamin A palmitate) ... powerful safe and effective anti-viral agent”
- Under the heading “The Scientific and Clinical Rationale for SAFALAB Corona Prevention 12 Pak Remedies”:
 - “Iodine, at appropriate dosages, kills all pathogens which infect the human body: viruses, bacteria, molds, fungi, yeasts and protozoa.”
 - “[S]elenium is a potent anti-viral mineral. Selenium facilitates enzymatic processes which enhance immune response to viral infections.”
 - “But in addition to synchronizing you to the world around you and enhancing your immune system to protect against environmental stressors, melatonin is also a powerful anti-viral agent This peer reviewed scientific article is [sic] just one of many which demonstrates the anti-viral benefits of melatonin”
 - “Melatonin and the Coronavirus.....Melatonin has been found to inhibit the action of an inflammasome known as NLRP3 – one of the primary inflammasomes involved in the exaggerated immune response seen in critical Coronavirus cases.

Melatonin’s ability to suppress the activation of NLRP3 has been found to:

 - Counteract severe inflammatory responses
 - Lower production of proinflammatory cytokines

- Lower infiltration of immune cells into lungs
- Reduce lung tissue injury

Melatonin's role in suppressing the inflammatory response is likely one of the reasons children under the age of 9 rarely present with severe symptoms when infected with Coronavirus. This is because young children can have up to 10 times the peak melatonin levels of older adults.

AND

Here is an impressive study. 'Melatonin, nitric oxide and ascorbic acid can reduce COVID-19 virulence by inhibiting NLRP3 inflammasomes to stop the perpetuation of cytokine storms.'

- "Melatonin plays an important role in your immune function. It has antioxidant and mitochondrial-protective functions, and has been shown to be effective against various bacterial and viral infections"
- "The inflammasome NLRP3 is a key culprit in acute respiratory distress syndrome and acute lung injury, both of which are potential outcomes of COVID-19 infection. Melatonin inhibits the activation of NLRP3 inflammasomes, thus offering potential protection against infection"
- "Vitamin D3 is an essential pro-hormone which can help you survive the Coronavirus. Studies show that taking vitamin D3 – the active form of vitamin D results in less severe respiratory infections and also required less antibiotic use."
- "ACETYLGLUTATHIONE

Glutathione is a powerful . . . anti-inflammatory agent which is tremendously valuable for people suffering from lung diseases and infections of the lung. The Coronavirus creates inflammation and what lowers native glutathione leading to further damage from inflammation. Once infected with the Coronavirus, you need glutathione . . .

RESEARCH ARTICLE

Glutathione-Capped Ag₂S Nanoclusters Inhibit Coronavirus Proliferation through Blockage of Viral RNA Synthesis and Budding."

- "WHAT TO DO TO PROTECT YOURSELF and your LOVED ONES?"

HERE IS YOUR 'TAKE ACTION NOW' MESSAGE

A competent medical doctor can rescue you if you are infected with the Coronavirus using intravenous infusion. . . But the minimum responsible protection which everyone should have stockpiled in his or her home is the Coronavirus Prevention 12 Pak available [HERE](#) from Safalab, Inc. for \$568." [The words "HERE from Safalab" contain a hyperlink that directs consumers to your website www.safalab.com/product/the-prevention-12-pak to purchase your product The Prevention 12 Pak.]

- "PREVENTION PROTOCOL

SOUL – take 1 packet first thing in the morning upon arising and one packet immediately before sleep

CORE – take 1 packet right before breakfast and right before dinner – can mix in 8 oz cold water for taste

Cellular Detox– take 10 drops under the tongue a day

Turb-O2™ – take 1 dropper full in water or juice or on food a day

AntiOxidant Assist (Vitamin C) 1000mg – take 1 three times a day

Melatonin 60mg – take 1 tiny scoop mixed in water or juice a day

Acetylglutathione – take 1 capsule take a day

Vitamin D3 5000 IU – take 1 a day

Methylselenocysteine 200 mcg – take 1 a day

IodAssist (iodine/dide blend) – take 1 capsule a day

Zinc Monomethionine and Citrate 30mg – take 1 a day

A-25 (Vitamin A palmitate) 2500 IU – take 1 a day”

- “ACUTE TREATMENT PROTOCOL (onset of cough, sore throat, headache, fever etc)

SOUL – take 1 packet 4x a day -first thing in the morning upon arising, one at 10 AM, one at 4 PM and one packet immediately before sleep

CORE – take 4x a day – 2 packets right before breakfast and 2 packets right before dinner – can mix in 8 oz cold water for taste

Cellular Detox– take 10 drops under the tongue twice a day

Turb-O2™ – take 1 dropper full in water or juice or on food twice a day

AntiOxidant Assist (Vitamin C) 1000mg – take 1-3 tables [sic] three times a day or more – push this dosage to bowel tolerance. When stools are loose, cut back.

Melatonin 60mg – take 1 tiny scoop mixed in water or juice a day three times a day

Acetylglutathione – take 1 capsule twice a day

Vitamin D3 5000 IU – take a 10 at first sign of cough or fever for 2 days then reduce to 1 a day

Methylselenocysteine 200 mcg – take 1 twice a day

IodAssist (iodine/dide blend) – take 1 capsule three times a day

Zinc Monomethionine and Citrate 30mg – take 1 twice a day

A-25 (Vitamin A palmitate) 2500 IU – take 6 at first sign of fever/cough and 6 again before sleep and repeat that high dose for no more than 4 days then drop back to 1 a day”

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 and COVID-19-Task-Force-CDER@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 and COVID-19-Task-Force-CDER@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 Jr -S**

Digitally signed by William A.
Correll Jr -S
Date: 2021.02.17 17:33:10
-05'00'

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

Sincerely,
**Donald D.
Ashley -S**

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People,
0.9.2342.19200300.100.1.1=2002198907,
cn=Donald D. Ashley -S
Date: 2021.02.09 13:21:26 -05'00'

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

**SERENA
VISWANATHAN**

Digitally signed by SERENA
VISWANATHAN
Date: 2021.02.09 10:57:10
-05'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission