



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



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

WARNING LETTER

VIA OVERNIGHT DELIVERY RETURN RECEIPT REQUESTED

February 5, 2019

Gold Crown Natural Products
Attn: Arnaldo Arias
12211 SW 121st Ter
Miami, FL 33186-5414

RE: 566223

Dear Mr. Arias:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.goldcrownnaturalproducts.com in October 2018 and has determined that you take orders there for the products New Ultra Colostrum, Melatonin with Valerian, Anamu & Llantén, and Circulation Max. The claims on your website establish that the products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Examples of some of the claims observed on your website that provide evidence that these products are intended for use as drugs include the following:

On the webpage for "Colostrum Ultra 3-Pack":

- "Colostrum has been shown to help eliminate allergies. Colostrum is a powerful anti-inflammatory compound, which can significantly benefit arthritis sufferers."
- "The lactoferrin included in the New Ultra Colostrum has been shown in some tests to help the human body's immune system fight cancer."
- "Colostrum supplements bought from Gold Crown Natural Products also has benefits for patients suffering from Alzheimer's disease. While there are ways to reduce the

damages for Alzheimer's by seeking its proper treatment, colostrum has in fact shown the benefits to help fight Alzheimer's disease."

- "[T]he number of diseases that colostrum cures has remained appropriately high. From chronic fatigue to diabetes [*sic*] to lupus and hemorrhoids, colostrum has been effectively accepted to be a major healer in the history of natural foods. This has been aided by its ability to satisfactorily provide treatments to various forms of complex diseases including other chronic and drug resistant diseases."

On the webpage titled "Melatonin Supplements/Melatonin with Valerian":

- "Melatonin pills are a popular natural treatment for insomnia."
- "Melatonin with Valerian for anxiety and insomnia is going to be all natural and the real deal when you order from Gold Crown Natural Products."
- "Melatonin supplements are used to help Alzheimer's disease. Melatonin is an effective anti oxidant and a free radical scavenger which is very useful to protect the cells from oxidative damage. Alzheimer's disease is caused due to this defect. Melatonin supplements such as melatonin with valerian tablets prevent the death of neurons caused by beta proteins which is a toxic substance which accumulates in the brain of the patients with this disorder. Many experiments have been conducted on this and it is proved that melatonin supplements are used to cure Alzheimer's disease."
- "Melatonin with valerian tablets help stop the mechanism that cause cancer . . ."
- "Melatonin supplements such [*sic*] melatonin with valerian is also used to treat sunburns, dementia, seasonal affective disorders, epilepsy etc."
- "Migraine headaches which are common in men and may be cured by taking a couple of mgs of melatonin with valerian tablets for one week. They can be relieved within a week by taking these melatonin supplements."

On the webpage titled "Anamu and Llantén 1100mg - 180 Capules 3-Pack":

- "The best anamu for cancer prevention: According to certain studies, Anamu has the potential to mitigate certain cancer tumors from developing."
- "Best anamu against viral infections: Based on numerous studies in 2002, Anamu has an antiviral property that prevents the growth and spread of certain stomach viruses."
- "Llantén is helpful against certain respiratory conditions and it is also helpful in addressing dysentery, conjunctivitis and diarrhea. Llantén is also proven to have helpful benefits to the blood. Llantén prevents bleeding and allows wounds to heal."

On the webpage titled "Circulation Max – 60 Capsules":

- "...Heart Supplements are necessary to mitigate the bad cholesterol and increase the presence of good cholesterol. Your cholesterol levels can be lowered with the help of Heart Supplements."
- "The Heart Supplements can be used to control your blood pressure."
- "Heart Supplements can also help mitigate blockages in the blood vessels . . ."
- "If you want to avoid the risk of heart disease or even diabetes, then getting blood

- circulation supplements daily can lessen those risks.”
- “Also, if your family has a history of diabetes, then it is possible that you could have that predisposition. It is vital that you take advantage of Heart Supplements to help regulate the blood.”
 - “Conditions like Buerger's Disease and Raynaud's disease can happen if the blood does not circulate across the body properly. By using the blood circulation supplements, it is possible to mitigate the conditions related to poor circulation.”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products New Ultra Colostrum, Melatonin with Valerian, Anamu & Llantén, and Circulation Max are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Accordingly, New Ultra Colostrum, Melatonin with Valerian, Anamu & Llantén, and Circulation Max fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with all requirements of federal law, including FDA regulations.

Unsubstantiated Advertising Claims

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. See *POM Wonderful LLC v. FTC*, 777 F.3d 478, 504-05 (D.C. Cir. 2015); *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp.

2d 1167, 1190, 1202 (N.D. Ga. 2008), aff'd, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

With regard to the advertising claims discussed above, please notify Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov within fifteen (15) working days of receipt of this letter, of 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.

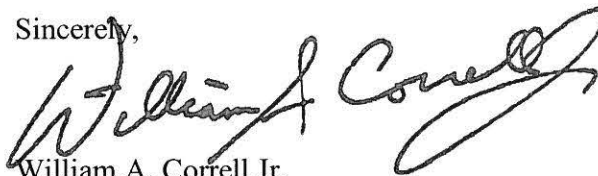
FD&C Act Violations

With regard to the FDA-related violations cited above, you should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Shawn Goldman, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,



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

MARY K. ENGLE Digitally signed by MARY K.
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Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

Cc:
Gold Crown Natural Products
782 NW 42nd Avenue
Miami, FL 33126