



**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

TEK Naturals
Trevor Rose, CEO
1985 Riviera Dr
103-127
Mount Pleasant, SC 29464

RE: 565026

Dear Mr. Rose:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.burn4her.com, www.burnertek.com, www.mindignite.com, www.tekmales.com, www.testotek.com, and www.teknaturals.com in September 2018 and has determined that you take orders there for your products BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK. FDA also reviewed your social media websites at www.facebook.com/TEKNaturals and www.twitter.com/TeKNaturals, which contain links to your website at www.teknaturals.com, and www.instagram.com/teknaturals, which contains links to your website at www.burn4her.com.

The claims on your websites establish that these 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 websites 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 website claims that provide evidence that your products are intended for use as drugs include the following:

On the "BURN4HER INGREDIENTS" page of your www.burn4her.com website:

- "BURN4HER's™ INGREDIENTS"
 - "Green Tea Extract ... Green Tea's polyphenols are scientifically proven to ... reduce a woman's risk for heart disease."
 - "Green Coffee Beans ... use of chlorogenic acid from green coffee bean extracts as an

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

important inhibitor of diet-related obesity and obesity-related metabolic syndrome ... [and] promote significant weight loss in individuals who suffer from morbid obesity. The extract has also shown positive effects in the regulation of high blood pressure and as an anti-diabetic supplement.”

- “Glucosamin ... reduce feelings of anxiety”
- “L-Carnitine ... is well-known for its anti-anxiety benefits.”

On the “BURNERTEK INGREDIENTS” page of your www.burnertek.com website:

- “BurnerTEK includes scientifically-researched, consistent potencies of the following ... ingredients:”
 - “Green Tea Extract ... possesses a wide range of therapeutic properties that are used in the treatment and prevention of some forms of cancer, Parkinson’s disease, human papilloma virus, and kidney stones.”
 - “Green Coffee Beans ... The extract has also shown positive effects in the regulation of high blood pressure and as an anti-diabetic supplement.”
 - “. . . Glucosamin is responsible for lowered LDL cholesterol”
 - “Cayenne Pepper ... has been the treatment of ear infections ... and even some forms of cancer...”
 - “[T]urmeric has a significant effect on obesity and insulin resistance.... Turmeric also helps combat the effects of obesity, notably inflammation...”
 - “L-Carnitine plays a vital role in the reduction of blood glucose levels.... It has also been shown to have a significant influence on the improvement of insulin sensitivity.”
 - “Vitamin B-Complex ... provid[es] a slew of benefits and therapeutic effects including ... resistance to disease, reduction of inflammation, [and] the prevention of memory loss...”
 - “Chromium Picolinate ... [is] used as a dietary supplement in the treatment and management of Type 2 Diabetes.... Chromium Picolinate supplies the body with its essential supply of elemental chromium. Elemental chromium plays a direct role in the control of LDL cholesterol, triglycerides, and indirectly prevents several types of heart disease.”

On the home page of your www.mindignite.com website:

- “Mind Ignite™ is a safe and highly effective alternative to Adderall. . . . Clinically shown to help diseases of the brain such as Alzheimer’s and even dementia.”
- “Adderall and similar drugs used to treat ADD and ADHD, are among the most abused drugs in the U.S. and abroad.... [T]he drugs can be highly addictive.... Mind Ignite™ is a safe and highly effective alternative to Adderall.”
- “In fact, some of [Mind Ignite’s™ sixteen] ingredients have been clinically shown to help diseases of the brain such as Alzheimer’s and even dementia.”
- “The ingredients in Mind Ignite ... are used to treat Alzheimer’s.”

On the “Mind Ignite™ Ingredients” page of your www.mindignite.com website:

- “Mind Ignite™ Ingredients”
 - “...Bacopa Monnieri is a natural ... anti-anxiety aid.”
 - “Alpha GPC ... is such a powerful nootropic ingredient that it is being tested as a possible treatment for Alzheimer’s patients.”
 - “Ginkgo Biloba is known to ... treat the symptoms of ADD and ADHD...”
 - “L-Tyrosine is an important amino acid that can ... reduce anxiety”
 - “The benefits of PS [Phosphatidylserine] ... counteract the symptoms of ADHD...”
 - “Huperzine A ... is also known to help treat Alzheimer’s.”
 - “St. John’s Wort Extract ... eases ... anxiety. It also has been known to alleviate

symptoms of ADHD.... The key compound in the herb is hypericin which is primarily responsible for helping with depression.”

- “Studies have shown that vitamins B-6 and B-12 specifically can help prevent cognitive decline and even help in preventing dementia and Alzheimer’s.”

On the “TEKMALE INGREDIENTS” page of your www.tekmales.com website:

- “TEKMALE INGREDIENTS”
 - “One particular clinical study of Korean Ginseng was done on a group of 45 impotent men. They supplemented with highly standardized Korean Ginseng for weeks and the study resulted in over 60% of the men no longer being impotent.”
 - “Muir Puama ... has the ability to fight ... premature ejaculation...”
 - “Yohimbe Bark Extract is actually used in a large number of countries as a prescription drug for erectile dysfunction.... Yohimbe Bark Extract is as close as you can get to taking Viagra, it’s that effective.”

On the “TESTOTEK INGREDIENTS” page of your www.testotek.com website:

- “TESTOTEK INGREDIENTS”
 - “Vitamin B6 ... helps in the production of serotonin, a chemical that is vital to fighting off depression and anxiety.”
 - “Vitamin B5 is essential because it helps regulate cholesterol...”
 - “Siberian ginseng ... has long been used to ... lower blood pressure, and help treat Alzheimer’s and diabetes.”

Additional examples of some of the claims on your www.teknaturals.com website include the following:

On the blog page titled “The Bedroom Benefits of Ginkgo Biloba” (Ginkgo Biloba is an ingredient in your products Mind Ignite and TEK Male):

- “[Ginkgo Biloba] has been used to act as a natural remedy for erectile dysfunction...”
- “Benefits of Ginkgo Biloba”
 - “Reduces risk for neurodegenerative diseases”
 - “Fights anxiety and depression”
 - “Treats adhd [sic]”
 - “Treats migraines”

On the blog page titled “The Many Benefits of Ginseng” (Ginseng is an ingredient in your product TEK Male):

- “Benefits of Ginseng”
 - “Anti-inflammatory agent”
 - “Helps prevent cancer”
 - “Reduces likelihood of getting erectile dysfunction”
- “... Ginseng could now be used as an alternative to Viagra.”
- “[Ginseng] has been used to treat people suffering from erectile dysfunction...”

On the blog page titled “New Mind Ignite Review from HealthToday.com,” there is a link to a review of your Mind Ignite product on <http://healthtoday.com/mind-ignite-review-top-nootropic-market/>. Your post states, “Check out this all new detailed review of our ... Mind Ignite™.” The linked article, which you endorsed, contains evidence of intended use in the form of a personal testimonial recommending or describing the use of Mind Ignite for the cure, mitigation, treatment, or prevention of disease. An example of such testimonials, which provide evidence that your product is intended for use as a drug,

includes:

- “I became addicted, right at the point that Adderall lost its effect.... I came across brain supplements, better known as nootropics, while researching natural ADHD cures. I was hesitant at first, however, after trying a few well-reviewed ingredients, my mind began to change ... consumers [are] switching from Adderall to nootropics.”

Your www.mindignite.com website also contains evidence of intended use in the form of personal testimonials. An example of such testimonials includes:

- “I take Mind Ignite every day. I have struggled with ADHD for many years and took Adderall but stopped because of the side effects. My friend recommended Mind Ignite and it works for me...”

Also, claims made on your Facebook page at <https://www.facebook.com/TEKNaturals>, which provides links to your website at www.teknaturals.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Facebook timeline page include the following:

- On August 17, 2018: “Muir Puama [an ingredient in TEK Male] ... provides a[n] ...effect in ... treating erectile dysfunction”
- On November 29, 2017, your post states, “Read this detail review for more information” and links to a review on <http://thesupplementreviews.org/nootropics/mind-ignite-review/>. The linked review, which you endorsed, provides additional evidence that your products are intended for use as drugs:
 - “Mind Ignite Review”
 - “[T]hese supplements are designed to [counter the symptoms of ADD and ADHD]”
 - “Nootropics are generally all-natural and safe-alternatives to Adderall and other prescription ADD/ADHD drugs.”
 - “Below we will outline these [Mind Ignite] ingredients so that you can get a feel for what each one’s specific role is.”
 - Ginkgo Biloba Extract ... will help to counteract the symptoms of ADD and ADHD”
 - “L-Tyrosine ... is a great natural alternative to the amphetamine that is found in drugs like Adderall.”
 - “Vitamins ... B6 and B12 specifically can reverse mental decline from aging or people who suffer with dementia or even Alzheimer’s.”

Claims on your Twitter page at www.twitter.com/TeKNaturals, which provides links to your website at www.teknaturals.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Twitter page include the following:

- On January 16, 2018, your post states, “Still getting great reviews for ... BurnerTEK™” and links to a review on www.iast.net/fat-burners/burnertek-review/. This linked review, which you endorsed, includes the following claim:
 - “BurnerTEK Ingredients”
 - “Green Coffee Bean Extract ... Chlorogenic acid, a primary ingredient found in green coffee bean extract, has been proven in various independent studies to

counter the effects of diabetes.”

Furthermore, claims made on your Instagram page at www.instagram.com/teknaturals, which provides links to your website at www.burn4her.com, provide additional evidence that your products are intended for use as drugs:

Posts by your company on your Instagram page include the following:

- On September 24, 2017: “Ever heard of nootropics? These are powerful natural brain boosters that serve as alternatives to the prescription drug Adderall.” [Your product Mind Ignite is described on its product page as a nootropic.]
- On July 9, 2017: “Here is a list of the major benefits men in our studies have reported experiencing since they started using TEKMale... ELIMINATE PREMATURE EJACULATIONS”

Your products BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK 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 BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK 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. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, BURN4Her, BurnerTEK, Mind Ignite, TEK Male, and TestoTEK 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 list 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 your firm complies 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. A court 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 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. ENGLE
Date: 2019.02.04
12:55:24 -05'00'

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission