WARNING LETTER

Jack B Goods Outlet Store

MARCS-CMS 566674 — NOVEMBER 07, 2018

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Product:
Dietary Supplements

Recipient:
Greg Lawrence
Jack B Goods Outlet Store
1024 Highland Cove Place
Ridgeland, MS 39157
United States

Issuing Office:
Center for Food Safety and Applied Nutrition
United States

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

November 7, 2018

Jack B Goods Outlet Store
Greg Lawrence
1024 Highland Cove Place
Ridgeland, MS 39157

Re: 566674

Dear Mr. Lawrence:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.jackbgoods.com (http://www.jackbgoods.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in October 2018 and has determined that you take orders there for the products Tianaa Red, Tianaa White, and Tianaa Green. 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. Additionally, even if the labeling for your products did not bear claims that make them drugs, and assuming the products meet the definition of "dietary supplement" in section 201(ff) of the Act [21 U.S.C. § 321(ff)], the products would be adulterated dietary supplements under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)] because they contain an unsafe food additive. 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.

Unapproved New Drugs and Misbranded Drugs

Examples of some of the website claims that provide evidence that your Tianaa Red, Tianaa White, and Tianaa Green products are intended for use as drugs include:

- "It has been our experience that there is a natural reaction that affects the serotonin receptor site providing an unparalleled solution to cravings for opiates. Kratom initially filled this need in providing mental clarity and energy without the crash. Now, these four alternatives can replicate the benefits of Kratom with perfection."

- "There has never been such a clear choice for pain and anxiety."

Your Tianaa Red, Tianaa White, and Tianaa Green products are not generally recognized as safe and effective for the above referenced uses and, therefore, the 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 CFR 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 Tianaa Red, Tianaa White, and Tianaa Green products 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, your Tianaa Red, Tianaa White, and Tianaa Green products 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)].

Adulterated Dietary Supplements

Even if your Tianaa Red, Tianaa White, and Tianaa Green products did not have claims that make them unapproved new drugs and misbranded drugs, your products would be adulterated dietary supplements under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)] because they contain an unsafe food additive. Your Tianaa Red, Tianaa White, and Tianaa Green products are labeled

as dietary supplements. The term "dietary supplement" is defined in section 201(ff) the Act [21 U.S.C. § 321(ff)]. Given that you have declared your Tianaa Red, Tianaa White, and Tianaa Green products as dietary supplements in the labeling of your products, we assume you have a basis to conclude that the products are “dietary supplements” under section 201(ff) of the Act [21 U.S.C. § 321(ff)].

The Supplement Facts labels of these products declare tianeptine as a dietary ingredient. Under section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)], a dietary ingredient is a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Tianeptine is not a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Accordingly, tianeptine is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)].

If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition,[1] it is a food additive. Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)]. Adulterated foods cannot be legally imported or marketed in the United States.

Section 201(s) of the Act [21 U.S.C § 321(s)] exempts dietary ingredients used in dietary supplements from the food additive definition. However, non-dietary ingredients intended for use in dietary supplements, such as the tianeptine used in your dietary supplement products, are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, a non-dietary ingredient added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for its intended use, unless it qualifies for another exception to the food additive definition.

Tianeptine is not generally recognized as safe under its conditions of use in your dietary supplement products. Because tianeptine does not qualify as a dietary ingredient and is not GRAS or otherwise exempt from the food additive definition, your Tianaa Red, Tianaa White, and Tianaa Green products are adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)] because they contain an unsafe food additive.

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 your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations 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 (mailto:Shawn.Goldman@fda.hhs.gov).

Sincerely,

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

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[1] Under section 201(s) of the FD&C Act [21 U.S.C. § 321(s)], the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act; (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.