U.S. FOOD & DRUG ADMINISTRATION

September 7, 2021

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

PHYTAG LABS - wecare@phytagesupport.com
George Rivera
12600 Hill Country Boulevard
Suite R-275
Bee Cave, Texas 78738

RE: 614514

Dear Mr. George Rivera,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, https://phytagelaboratories.com, in August of 2021 and has determined that you take orders there for your "GLUCOTYPE2" product. Additionally, we reviewed your product listings and your seller profile on your Amazon storefront on www.Amazon.com, which you operate under the name "Phytag Labs." You are also advised that the Federal Trade Commission reviewed your websites in August 2021.

The claims on your website and Amazon storefront establish that your product is a drug 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 it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product 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.

Examples of some of the website claims that provide evidence that this product is intended for use as a drug include:

On your webpage titled, "GLUCOTYPE2" under Details:

- "CONTROL YOUR BLOOD SUGAR NOW"
- "GlucoType2™ is breakthrough, all natural blood sugar control support supplement that's not just helping support the fight against Type 2 diabetes, it help in reducing inflammation, lowering cholesterol, reducing nerve pain and even helps with various types of body fungus"
- "[J]ust one GlucoType 2™ capsule each day, for 30 days (90 days recommended), the anti-diabetic properties of the ingredients contained in GlucoType 2™ work their best to

support the fight against Type 2 diabetes and a number of other possible health ailments, before their onset."

- "[L]owers elevated blood sugar levels and blood pressure in Type 2 Diabetes across the day…"
- "[R]egulates blood sugar levels, … and helps in the fight against diabetes & heart attacks"
- "[R]ich in corosolic acid (a substance found to possess blood-sugar-lowering…and anti-inflammatory properties)…"
- "[C]onquers insulin resistance and also shown to be useful in the treatment of certain classes of non-insulin-dependent diabetes"

On your Amazon.com storefront product page for GLUCOTYPE2:

- "GlucoType 2 Blood Sugar Metabolism Supplement Stabilizer… Type 2 Diabetes Optimizer…"
- "Bitter Melon [an ingredient in the product] lowers elevated blood sugar levels and blood pressure in Type 2 Diabetes"
- "Banaba [an ingredient in the product] rich in corosolic acid (a substance found to possess blood-sugar-lowering … and anti-inflammatory properties)"
- "Gymnema Sylvestre [an ingredient in the product] …useful in the treatment of certain classes of non-insulin-dependent diabetes"

Your "GLUCOTYPE2" product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. 321(p)]. With certain exceptions not applicable here, 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 product "GLUCOTYPE2" is intended for treatment of one or more diseases that, with certain exceptions not applicable here, 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 product safely for its intended purposes. Accordingly, your GLUCOTYPE2 product fails to bear adequate directions for its intended use and, therefore, the product is 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 this misbranded drug violates section 301(a) of the Act [21 U.S.C. 331(a)]

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within 15 working days, 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 Act, include your reasoning and any supporting information for our consideration.

Your written reply to the above violations should be directed to Aaron Dotson with the FDA via email at CFSANResponse@fda.hhs.gov. If you have any questions, you may also email at CFSANResponse@fda.hhs.gov.

FTC Cease and Desist Demand: In addition, the Federal Trade Commission has determined that 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 a reasonable basis consisting of 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. *POM Wonderful LLC,* 155 F.T.C. 1, 60-61, (2013), *aff'd in relevant part*, 777 F.3d 478 (D.C. Cir. 2015); *Daniel Chapter One*, FTC Dkt. No. 9239, 2009 WL 5160000 at *16-19 (F.T.C. Dec. 24, 2009), *aff'd*, 405 Fed. Appx.505 (D.C. Cir. 2010); *Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988), *aff'd*, 884 F.2d 1489, 1496 (1st Cir. 1989); see also, *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*, WL 5160000 at *17-19.

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. Notice is hereby given that you must cease and desist from making any claim that a product and prevent, treat, or cure diabetes without competent and reliable scientific evidence consisting of well-controlled human clinical studies substantiating that the claims are true. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. In

addition, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of a disease may be subject to a civil penalty of up to $43,792 per violation pursuant to Section 5(m)(1)(B) of the FTC Act, 15 U.S.C. § 45(m)(1)(B), and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). With regard to the advertising claims discussed above, please notify Richard Cleland of the FTC 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 FTC's concerns.

Sincerely,

Glenn T. Bass -S

Digitally signed by Glenn T. Bass -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Glenn T. Bass -S, 0.9.2342.19200300.100.1.1=1300189586
Date: 2021.09.07 11:49:01 -04'00'

Glenn Bass Acting
Deputy Director
Office of Compliance
Center for Food Safety
and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

Digitally signed by SERENA VISWANATHAN
Date: 2021.09.02 08:59:35 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission