U.S. FOOD & DRUG ADMINISTRATION

September 7, 2021

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Live Good Inc.- hello@sell2help.com
Jean Fuente
860 NW 27th St.
Suite 051-51425
Miami, FL 33122

RE: 614575

Dear Mr. Jean Fuente,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, https://berrygen.com/, in August 2021, and has determined that you take orders there for your "Berry Gen Sugar Control" product. We have also reviewed your social media websites at https://www.facebook.com/ColagenoBerryGenRestore/ and https://www.instagram.com/berrygenrestore/ that you link to directly from your website where you can purchase your 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, "Berry Gen Sugar Control". You are also advised that the Federal Trade Commission reviewed your websites in August 2021.

The claims on your website, social media webpages, 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 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 includes:

On your webpage under product description:

- "Berry Gen Sugar Support is a treatment … that helps reduce blood sugar levels, control glucose, improve conditions for diabetic people, and protect the pancreas, as well as improve skin problems and joint pain."

- "Helps control diabetes"

- "Helps regulate blood sugar and insulin levels"

On your social media Facebook page:

In Spanish:

- "Llegó el colágeno que te ayuda a controlar la diabetes y regular los niveles de azúcar e insulina en sangre." translated to "Collagen has arrived that helps you control diabetes and regulate blood sugar and insulin levels." [May 18, 2020]

In Spanish:

- "Controla la glucosa y mejora tu calidad de vida tomando Berry Gen Sugar. Además, regula niveles de azúcar e insulina en sangre" translated to "Control glucose and improve your quality of life taking Berry Gen Sugar. In addition, it regulates blood sugar and insulin levels" [May 28, 2020]

In Spanish:

- "Ayuda a controlar los niveles de azúcar ...#diabetes #diabetescontrol" translated to "Helps control sugar levels ... #diabetes #diabetescontrol" [September 12, 2020]

On your social media Instagram page:

- "#berrygensugarcontrol Ayuda a regular el azucar en la sangre y Promueve un mejor funcionamiento del pancreas." translated to "#berrygensugarcontrol Helps regulate blood sugar and Promotes better functioning of the pancreas." [May 7, 2021]

- Photo states: "Sugar CONTROL" with the caption that states: "#berrygensugarcontrol ayuda a los diabéticos con el tipo 2 brindando regulación, protección celular y menos complicaciones." translated to "#berrygensugarcontrol helps type 2 diabetics with providing regulation, cell protection and fewer complications." [February, 21 2021]

On your Amazon product page:

- "Berry Gen: … [H]elps regulate blood sugar levels"

- "[R]egulate your blood sugar: Enjoy the way you control your body's glucose levels with Berry Gen Sugar Control … providing blood sugar support"

- "Berry Gen Sugar Control is our natural approach to helping you regulate your blood sugar and insulin levels …"

On your Amazon product page (3 pack):

- "Berry Gen Sugar Control … Anti-inflammatory …"

- "BERRY GEN SUGAR CONTROL SUPPORT– help reduce inflammation and support improved blood sugar balance … support improved blood pressure"

- "Berry Gen Sugar Support is a supplement based on Hydrolyzed Collagen, Milk Thistle, Bitter Melon Extract, Alpha Lipoic Acid and Cinnamon Extract, designed to help reduce blood sugar levels, control glucose …"

Your "Berry Gen Sugar Control" product is not generally recognized as safe and effective for the above referenced uses and, therefore, this 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 ""Berry Gen Sugar Control" 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 "Berry Gen Sugar Control" 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=13001899586
Date: 2021.09.07 11:59:28 -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 08:55:29 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission