U.S. FOOD & DRUG ADMINISTRATION

September 7, 2021

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Pharmaganics LLC - info@diabetesdoctor.com
Tom Redmond III, CEO
8475 Parley Lake Rd
Waconia, MN 55387

RE: 614576

Dear Mr. Tom Redmond III:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.diabetesdoctor.com, in August 2021 and has determined that you take orders there for your "Diabetes Doctor Pre-Diabetes" and "Diabetes Doctor Blood Sugar 24 Hour" products. We have also reviewed your social media websites at https://www.facebook.com/naturaldiabetesdoctor and https://www.instagram.com/diabetesdoctor/, which direct consumers to your website www.diabetesdoctor.com to purchase your products. Additionally, we reviewed products listings and seller profile on your Walmart webpage on https://www.walmart.com/, and your product listings and seller profile on your Amazon storefront on https://www.Amazon.com, both which you operate under the name, "Diabetes Doctor". You are also advised that the Federal Trade Commission reviewed your websites in August 2021.

The claims on your website, social media webpages, Amazon storefront, and Walmart webpage establish that your 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.

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

On your "Diabetes Doctor Pre-Diabetes" product page on your website:

- "Fights Insulin Resistance"

- "Maintain healthy function of vital diabetes organs"

- "Curcumin/Turmeric [ingredient in product]…In a research study of people with pre-diabetes, taking curcumin for 9-months significantly reduced the number of prediabetic individuals who eventually developed Type 2 diabetes. Curcumin treatment appeared to support healthy function of β-cells, the insulin producing cells of the pancreas."

- "Magnesium [ingredient in product]...Research shows that a 100 mg/day increase in magnesium intake is associated with a 15% risk reduction for developing type 2 diabetes…"

- "Vitamin D3 [ingredient in product] Clinical research has demonstrated that in people without diabetes, increasing blood levels of vitamin D is associated with a lower risk of developing type 2 diabetes. Our formula uses the activated form of Vitamin D (D3)."

On your "Diabetes Doctor Blood Sugar 24 Hour" product page on your website:

- "Studies have shown cassia cinnamon [ingredient in product] at high doses can reduce fasting blood sugars by 25mg/dL

- "Milk Thistle [ingredient in product] … has been clinically proven to fight resistance for significant benefits on blood sugar health"

    - "Lower fasting blood sugars by 11%"
    - "Lower insulin needs by 14%"
    - "Lower HbA1C by 1.5%"
    - "Lower abnormal liver enzymes in patients with non-alcoholic fatty liver disease"
    - "Lower protein in the urine (marker of kidney damage) in patients with diabetic kidney disease"

- "Bilberry [ingredient in product] …shown improved retinal (eye) circulatory health in adults with diabetic retinopathy after 6 months"

- "Banaba [ingredient in product] acts as a natural insulin sensitizer to support healthy blood sugar and A1C . …[B]anaba can reduce blood sugars by 30%, and A1C by 0.65%"

On your social media Facebook page:

- "Research shows that cinnamon [ingredient in product] does NOT work to lower blood sugars….. unless used at doses of 500-1000 mg/day! Blood Sugar 24 Hour Support includes Cinnamon at the right dose (750 mg/day)" [August 4, 2020]

- In the comments an individual asks, "Can this be taken as a diabetes preventative?" and Diabetes Doctor responds with "Check out our products for Pre Diabetes https://diabetesdoctor.com/collections/pre-diabetes" [August 4, 2020]

On your social media Instagram page:

- "[C]omprehensive product that is designed to help you meet your daily diabetes needs from blood sugar control to diabetes specific organ health …. help that insulin function better and cut through insulin resistance …" [March 5, 2021]

On your Amazon.com storefront product page for your "Diabetes Doctor Pre-Diabetes" product:

- "Diabetes Doctor Early Defense – Pre-Diabetes and Diabetes Support … Stabilize Blood Sugar Levels"

- PROMOTES GOOD HEALTH: "Early Defense is specially designed to support your prediabetes needs."

- "ESSENTIAL NUTRIENTS: Early Defense contains a blend of key ingredients like Magnesium and Vitamin D3 [ingredients in the product] that are critical in diabetes health."

On your Amazon.com storefront product page for your "Diabetes Doctor Blood Sugar 24 Hour" product:

- "Diabetes Doctor Daily Support – 7 in 1 Blend for Daily Diabetes Needs and High Blood Sugar Regulation - Target Insulin Resistance and Sensitivity, Organ Health …"

- "REVOLUTIONARY BLEND AND HIGH DOSES: … natural ingredients needed for daily Diabetes support and blood sugar regulation"

- "COMBAT INSULATION RESISTANCE: Diabetes Doctor's powerful blend of Cinnamon, Banaba, Magnesium, and Chromium helps promote healthy insulin function …"

On your Walmart.com product listing page for "Diabetes Doctor Blood Sugar 24 Hour":

- "Take control of your diabetes naturally with the help of Blood Sugar 24 hour Supplement by Diabetes Doctor. Help maintain healthy blood sugar levels …which helps your body's natural insulin work better."

- "This product is not only a multivitamin but has been specifically designed to target the root cause of high blood sugar and Type 2 diabetes"

Your "Diabetes Doctor Pre-Diabetes" and "Diabetes Doctor Blood Sugar 24 Hour" 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)]. 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 "Diabetes Doctor Pre-Diabetes" and "Diabetes Doctor Blood Sugar 24 Hour" products are 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 "Diabetes Doctor Pre-Diabetes" and "Diabetes Doctor Blood Sugar 24 Hour" products 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 11:52:40 -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 08:58:55 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission