September 7, 2021

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

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

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"

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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

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)].

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.