U.S. FOOD & DRUG ADMINISTRATION

**September 7, 2021**

**VIA OVERNIGHT DELIVERY**
**RETURN RECEIPT REQUESTED**

Lysulin, Inc.
John Burd
4930 Bradshaw Ct.
San Diego, CA 92130

RE: 614517

Dear Mr. John Burd,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, https://lysulin.com/, in August 2021and has determined that you take orders there for your "Lysulin Weight Loss Shake," "Lysulin Diabetes and Prediabetes Chewables," "Lysulin Diabetes and Prediabetes Liquid," "Lysulin Diabetes and Prediabetes Capsules," and "Lysulin Diabetes and Prediabetes Powder" products. We have also reviewed your social media websites at https://www.instagram.com/lysulin_usa/ and https://www.facebook.com/lysulindiabetesmanagement, which direct consumers to your website https://lysulin.com/ to purchase your products. Additionally, we reviewed your seller profile and product listings on your Amazon storefront on www.Amazon.com, which you operate under the name, "Lysulin, Inc." 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 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 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 these products are intended for use as drugs include:

On the homepage, section "What's in Lysulin?":

- "The combination and high level of these active ingredients have been shown to help maintain healthy A1c blood sugar levels in diabetics and prediabetics."

- "Lysulin is patented and proven in a human clinical study to help people with diabetes and prediabetes maintain healthy levels of A1c blood sugar."

On the webpage titled, "Lysulin ® Weight Loss Shake" under Details:

- "[D]aily serving of patented Lysulin ® to reduce blood glucose"
- "The Lysulin® Weight Loss Shake is the ONLY SHAKE with the patented Lysulin® ingredient to reduce Glucose from the blood stream …"

Under Label & Specifications:

- "Drink this shake every day … daily serving of patented Lysulin® to reduce blood glucose"
- "Reduces Glucose in the blood stream"

On your social media Instagram page:

- "Lysulin Nutritional Support for People With Diabetes & Prediabetes"
- "Lysulin…clinically shown to help people with diabetes or pre-diabetes…works like a sponge to remove Glucose from your bloodstream…#type2diabetic #diabetescare …#insulindependent #diabetes #insulinresistance…" [April 26, 2021]
- "What is Lysulin? Formulated by a renowned diabetes scientist, Lysulin … help maintain healthy A1c blood sugar levels in diabetics and pre-diabetics." [August 20, 2020]

Your social media Instagram page also contains evidence of intended use in the form of personal testimonials recommending or describing the use of products for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

- "I am 64 years old and have Type 1 diabetes… I just finished my one month trial of Lysulin and am pleased to report that my starting HbA1c of 10.5% in October dropped to 9.5% in just one month. I plan to keep using Lysulin to see how low I can get my HbA1c. …" [November 27, 2018]
- "I have had Type 2 diabetes since May 2017… My HbA1c was 7.4 in October of 2017. I tested my HbA1c with the home HbA1c test kit on 9-16-18 and it was 6.6% I started taking Lysulin and on 11-12-18 the lab tested my HbA1c and it had dropped to 6.2% …" [December 4, 2018]

On your social media Facebook page:

- "Lysulin Weight Loss Shake Nutritional Support For Diabetics & Prediabetics"

- "Let Lysulin be your partner for better diabetes management"

- "Lysulin provides people with diabetes and pre-diabetes with the nutritional support they need to maintain healthy levels of Insulin Resistance and A1c."

- "Our mission at Lysulin is to help people with Prediabetes or Type 2 Diabetes prevent, manage, or in some cases even completely reverse the disease."

Your social media Facebook page also contains evidence of intended use in the form of personal testimonials recommending or describing the use of products for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

- "This has really helped lower my blood sugars. … Just had my lab work done and my a1c went from 7.8 to 6.2 …" [February 24, 2021]

- "I have had Type 2 diabetes for over 20 years and have had health problems due to my diabetes. I am very satisfied with Lysulin after using for 2 months …" [February 13, 2021]

On your Amazon.com storefront product page for "Lysulin Diabetes and Prediabetes Capsules":

- "Lysulin… Natural Diabetic Formula to Lower Blood Glucose for Type 2 Diabetes Or Prediabetes…"

- "BLOOD SUGAR CONTROL: Lysulin helps lower blood glucose, glycated proteins, and A1c levels for people with type 2 diabetes, prediabetes, and anyone at risk of developing diabetes and metabolic syndrome."

- "IMPROVE LIPIDS AND BLOOD PRESSURE: Lysulin… and shown to lower blood glucose and HbA1c levels."

- "Lysulin is an all natural supplement to lower blood sugar"

- "CLINICALLY TESTED: "… Lysulin can help to lower blood glucose and A1c levels while improving the lipid profile in prediabetes and diabetes"

Your "Lysulin ® Weight Loss Shake," "Lysulin Diabetes and Prediabetes Chewables," "Lysulin Diabetes and Prediabetes Liquid," "Lysulin Diabetes and Prediabetes Capsules," and "Lysulin Diabetes and Prediabetes Powder" 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 ""Lysulin ® Weight Loss Shake," "Lysulin Diabetes and Prediabetes Chewables," "Lysulin Diabetes and Prediabetes Liquid," "Lysulin Diabetes and Prediabetes Capsules," and "Lysulin Diabetes and Prediabetes Powder" 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 "Lysulin ® Weight Loss Shake," "Lysulin Diabetes and Prediabetes Chewables," "Lysulin Diabetes and Prediabetes Liquid," "Lysulin Diabetes and Prediabetes Capsules," and "Lysulin Diabetes and Prediabetes Powder" 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
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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 08:56:51 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission