U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

May 20, 2021

EU Natural Inc
Vinay Amin, President
2654 W Horizon Ridge Pkwy
Ste B5-93
Henderson, NV 89052
info@eunatural.com

RE: 605871

Dear Mr. Amin,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.store.eunatural.com, in March 2021 and has determined that you take orders there for the products "CONCEPTION Female Fertility Prenatal" and "CONCEPTION MEN Male Fertility". We have also reviewed your social media website at www.instagram.com/eunatural/; this website directs consumers to your website www.store.eunatural.com to purchase your products. You are also advised that the Federal Trade Commission reviewed your websites in May 2021.

The claims on your website 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 the following:

On your webpage titled "10 Best Natural Fertility Herbs and Boosters for Women":

- "Myo-Insitol [sic] [an ingredient in "CONCEPTION Female Fertility Prenatal"] . . . When taken as a supplement, it can absolutely combat infertility issues. One study looked at 25 women with Polycystic Ovary Syndrome. They were given myo-insitol [sic]

(combined with folic acid) two times a day for 6 months. 88% ended up having 'at least one spontaneous menstrual cycle' during this treatment. Of that 88%, 72% maintained normal ovulatory activity. Plus, 10 of the 25 women actually got pregnant while on myo-insitol [sic]. Another study that looked specifically at women with Polycystic Ovary Syndrome found myo-insitol [sic] improves ovarian cells and embryo quality when the woman is in the ovarian stimulation process."

- "[W]hen you add in the vitamin D [an ingredient in "CONCEPTION Female Fertility Prenatal"] you not only improve polycystic ovary syndrome, you also can improve the income [sic] on in-vitro fertilization."

On your webpage titled "4 Beneficial Ways To Treat Endometriosis Naturally":

- Top choices for those with endometriosis include…B6…Chaste Tree [both ingredients in "CONCEPTION Female Fertility Prenatal"]… If you are currently dealing with infertility as a result of endometriosis, try to find prenatal vitamins/supplements that include some of these natural remedies."

On your webpage titled "Ashwagandha: Benefits, side effects and how to take it?" [ashwagandha is an ingredient in "CONCEPTION Female Fertility Prenatal" and "CONCEPTION MEN Male Fertility"]:

- "…[B]enefits that Ashwagandha is believed to have…include: …Helping with depression, Treating arthritis…Reducing blood sugar levels, Stopping cancer growth, Helping with insomnia"
- "Ashwagandha is also commonly linked to being a natural way to help overcome anxiety… taking Ashwagandha extract can be hugely beneficial for those living with anxiety."
- "Ashwagandha has been linked to increasing insulin secretion and improving insulin sensitivity in muscle cells and could help treat diabetes."
- "Ashwagandha extract had [sic] antidiabetic properties, including decreased blood glucose level, preventing hyperinsulinemia, and improved glucose tolerance."
- "…Ashwagandha demonstrates anti-cancer effects against several cancer cell lines."
- "…[A]shwagandha selectively kills tumor cells."
- "…natural source for safe anticancer medicine."
- "…Ashwagandha is also said to help with insomnia."

Your social media website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of "CONCEPTION Female Fertility Prenatal" for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include the following:

Claim featured on Instagram (www.instagram.com/eunatural/):

- "Why did I start taking Conception from @eunatural you may ask... I possibly have PCOS and Myo Inositol [an ingredient in "CONCEPTION Female Fertility Prenatal"] has been shown to help regulate Insulin and regulate your cycle. I'm excited to add this into my #fertilityjourney"

Your products "CONCEPTION Female Fertility Prenatal" and CONCEPTION MEN Male

Fertility" are not generally recognized as safe and effective for the above referenced uses and, therefore, the 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 "CONCEPTION Female Fertility Prenatal" and "CONCEPTION MEN Male Fertility" products are intended for treatment of one or more diseases that 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 products safely for their intended purposes. Accordingly, your "CONCEPTION Female Fertility Prenatal" and "CONCEPTION MEN Male Fertility" products fail to bear adequate directions for their intended use and, therefore, the products are 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 these misbranded drugs 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 should be directed to Aaron Dotson, Compliance Officer, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive,

Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, you may also contact Aaron Dotson at aaron.dotson@fda.hhs.gov.

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. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. 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. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Michael W. Roosevelt -S

Digitally signed by Michael W. Roosevelt -S
Date: 2021.05.20 10:53:55 -04'00'

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

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Date: 2021.05.19 09:20:26 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission