U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

May 20, 2021

Fertility Nutraceuticals LLC
Norbert Gleicher
21 E 69th St
New York, NY 10021

RE: 605595

Dear Mr. Norbert Gleicher,

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites at the Internet addresses, www.fertilitynutraceuticals.com and www.fertilitysupplementstore.com in March 2021 and has determined that you take orders there for the products "CONFLAM- Forte™," "FERTINATAL® DHEA", and "OVOENERGEN™ CoenzymeQ10". You are also advised that the Federal Trade Commission reviewed your websites in May 2021.

The claims on your websites and literature included with a sale of "CONFLAM-Forte™" 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 the website www.fertilitynutraceuticals.com:

On the Fertility Supplements Page:

- "[B]est fertility supplements to boost your chance of pregnancy or improve your IVF success rate…include… FERTINATAL® Women's DHEA 25 mg… "OVOENERGEN™ Women's CoQ10 333 mg…."

On the News Tab:

- "[O]ne of the best defenses against miscarriage is to make sure your body is ready for conception and pregnancy at the cellular level. Our supplements are designed to do just that. A 2007 study demonstrated that DHEA decreases the miscarriage rate of women"

Article titled: "*4 Important Fertility Questions Answered*":

- "Fertinatal Fertility DHEA has been show in multiple studies to . . . reduce miscarriage risk."

On the website www.fertilitysupplementstore.com:

On the "Supplement Guide" page:

- "FERTINATAL® DHEA For Women is recommended for:… Women . . . receiving fertility treatment..."
- "CONFLAM-Forte™ . . . is recommended for: Women with evidence of inflammation. . . Women with inflammatory diseases including autoimmune diseases . . . Women with severe allergies . . . Women with PCOS and with obesity…"
- "OVOENERGEN ™ CoenzymeQ10 . . . is recommended for: Women who are trying to get pregnant either on their own, or with fertility treatments . . ."
- "Egg Health Power Pack I [which combines FERTINATAL® DHEA with OVOENERGEN ™ CoenzymeQ10] is recommended for:… Women who have low ovarian reserve . . . Women . . . with high miscarriage risk"

On the "CONFLAM-Forte™" page:

- "…Fertility Doctors Recommend Conflam-Forte . . . Alleviates overactive inflammation"
- "CONFLAM-Forte™ . . . is especially recommended for: Women with evidence of inflammation . . . Women with inflammatory diseases including autoimmune diseases . . . Women with severe allergies…Women with PCOS and with obesity…"

The literature that you enclose, shipped with a sale of the "CONFLAM-Forte™" product, contains evidence that your product is intended for use as drug, including the following:

"CONFLAM Forte™" product insert:

- "POTENTIAL BENEFITS: Studies have suggested that calming the immune system by modulating inflammation can enhance female fertility, improve pregnancy chances with. . . IVF, and lower miscarriage risks"
- "[W]ell suited for women with infertility, a history of implantation failure, chemical pregnancies and miscarriages or with known inflammatory conditions, like obesity, polycystic ovary syndrome (PCOS), severe allergies and autoimmune conditions."

"CONFLAM-Forte™" product label:

- "[C]omprehensive Inflammation-Modulating Nutritional Supplement for Fertility"
- "Since excessive inflammation is very frequent, CONFLAM-Forte™ . . . is especially recommended for . . . women with evidence of inflammation . . . women with inflammatory diseases including autoimmune diseases . . . women with severe allergies, PCOS and obesity."

Your products "CONFLAM Forte™", "FERTINATAL® DHEA", and "OVOENERGEN™ CoenzymeQ10" 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 "CONFLAM Forte™" product is 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 product safely for its intended purposes. Accordingly, your "CONFLAM Forte™" product fails to bear adequate directions for its intended use and, therefore, this 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 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 10:55:27 -04'00'

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

Sincerely,

SERENA VISWANATHAN
Digitally signed by SERENA VISWANATHAN
Date: 2021.05.19 09:16:46 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission