



**FDA U.S. FOOD & DRUG
ADMINISTRATION**



WARNING LETTER

**VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED**

May 20, 2021

SAL NATURE LLC/FertilHerb
Hind Tatni
1621 Central Ave
Cheyenne, WY 82001-4531

RE: 605597

Dear Mr. Hind Tatni,

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.fertilherb.com, in March 2021 and has determined that you take orders there for the product “FertilHerb for Women”. You are also advised that the Federal Trade Commission reviewed your website in May 2021.

The claims on your website establish that the product is a drug 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 it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product 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 product is intended for use as a drug include the following:

On the “FertilHerb for Women” product webpage:

- “FertilHerb® supplements ... are a perfect natural alternative to fertility drugs or invasive treatments.”
- “Myo-inositol [an ingredient in “FertilHerb for Women”] – Many studies found Myo-inositol to be a simple and safe treatment capable of restoring ... fertility in most patients with PCOS.”
- “Iron [an ingredient in “FertilHerb for Women”] – ...[I]ron supplementation could decrease the risk of ovulatory infertility.”

Article titled “Vitex and fertility in women”:

- “Doctors use Vitex [an ingredient in “FertilHerb for Women”] to treat mild endometriosis or prevent its advancement. It has also been effective in treating amenorrhea, which is the lack of menstruation, as well as irregular menstruation, which can hinder fertility greatly.”

Article titled “Fertility Supplement Myo-inositol aka Inositol”:

- “A case study was carried out where German gynecologists evaluated 3602 women who were suffering from Polycystic Ovary Syndrome. They took Myo-inositol and folic acid [ingredients in “FertilHerb for Women”] every morning for 2-3 months... 2520 women restored to normal cycles while 545 of them got pregnant.”

Article titled “Female Fertility Friendly Vitamins – Fertility Vitamins”:

- “[V]itamin B6 [an ingredient in “FertilHerb for Women”] is also helpful with the luteal phase defect.”
- “Vitamin B12 [an ingredient in “FertilHerb for Women”] .. reduces the chances of miscarriage.”

Your “FertilHerb for Women” product is not generally recognized as safe and effective for the above referenced uses and, therefore, this product is a “new drug” 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 “FertilHerb for Women” 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, “FertilHerb for Women” 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 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 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
Acting Director
Office of Compliance
Center for Food Safety and
Applied Nutrition
Food and Drug Administration

Sincerely,

SERENA

Digitally signed by
SERENA VISWANATHAN



VISWANATHAN Date: 2021.05.19 09:17:53
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission