U.S. FOOD & DRUG ADMINISTRATION

# WARNING LETTER

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

May 20, 2021

NS Products, Inc.
Wolfe Vaughn and Craig
Sheralyn 11721 State Ave
Marysville, WA 98271

RE: 605706

Dear Wolfe Vaughn and Craig Sheralyn:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.naturacure.net in March 2021 and has determined that you take orders there for the product "NaturaCure." 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 home page:

- "You avoid expensive surgical procedures, injections and ineffective treatments. . . NaturaCure may replace conventional fertility treatments…."

On the "ABOUT FERTILITY" page:

- "NaturaCure works with your body, eliminating the root cause of your specific infertility disorder (such as: ovarian cysts, uterine fibroids, endometriosis, high FSH, PCOS etc.)…."

- "You will get pregnant very fast and give birth to healthy children regardless of . . . how severe or chronic your infertility disorder."

On the "HOW IT WORKS" page:

- "If you suffer from infertility, tried every prescription, patch and injection the doctors have prescribed but nothing works – and want a solution that really works – then you need to try . . . NaturaCure."
- "Depending on individual customers and the types of infertility treated, success rates ranged from about 50% up to 98%. Included in these statistics are cases of infertility involving: . . . Obstruction of the fallopian tubess [*sic*] [,] Amenorrhea[,] Absent ovulation[,] Endometriosis[,] Uterine fibroids[,] . . . None liquidification of semen [sic][,] Tubal blockage[,] . . . Previous tubal ligation"
- "Discovery NaturaCure's Award Winning Herbal Formulation"
    - "Bee Propolis - is beneficial for autoimmune related fertility issues such as recurrent miscarriage due to immunological response (mother's body attacks and rejects the fetus), autoimmune related premature ovarian failure and antisperm antibody."
    - "Raspberry Fruit - Relieves impotence . . ."

Your website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of NaturaCure for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

On the "CUSTOMER REVIEWS" page:

- "I had a miscarriage in June 2010 & have been trying to conceive ever since . . . In April 2011 I decided to order NaturaCure. Started taking it in May & I am now 7 weeks pregnant! . . . THIS REALLY WORKS!!!!"

Your product "NaturaCure" is not generally recognized as safe and effective for the above referenced uses and, therefore, the 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 "NaturaCure" 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, "NaturaCure" 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 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 10:50:32 -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 09:19:15 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices Federal Trade Commission