WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

May 20, 2021

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

- “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 thec custea.3 (nf)32.7 (e)d [(ha)10c0.4 (t)a (n

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, MD 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),

Michael W. Roosevelt -S

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Date: 2021.05.20 10:50:32 -04'00'