

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 to the above violations should be directed to Aaron Dotson with the FDA via email at CFSANResponse@fda.hhs.gov. If you have any questions, you may also email at CFSANResponse@fda.hhs.gov.

FTC Cease and Desist Demand: 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*
