



## ***Responding to Regulatory Agency Warning Letters***

How you respond to an FTC warning letter is largely dependent on risk tolerance, and your understanding of (and compliance with) regulatory laws and regulations related to deceptive marketing as governed by the FTC, as well as restrictions on dietary supplements as outlined in the Dietary Supplement Health and Education Act of 1994 (DSHEA). For additional background on FTC regulatory actions around COVID-19, please see the AANP's [Fact Sheet on Regulatory Agency Warning Letters](#).

### **Context:**

The primary regulatory interest of the FTC is to curtail advertisement for products or services that are deceptive or unsubstantiated. FTC is primarily focused on the commercialization of claims that products or services treat or prevent COVID-19 specifically.

### **General Recommendations:**

1. Do respond to FTC. State that you are in receipt of the letter, that you intend to cooperate and intend to make changes you believe are responsive.
2. Do respond by the due date.
3. Do not admit wrong-doing, as this will be an ongoing dialogue largely up to subjective interpretation. Consider including a statement such as "I am not making any admission of wrong-doing or violation of any requirement for any purpose. I continue to believe that the statements made on our website were accurate, based upon reliable and competent scientific evidence and in the public interest."
4. Provide copies of changes or a plan, including any disclaimers you intend to add.
5. Treat the FTC analyst as a colleague who is attempting to help you comply rather than a hostile force, and they should act in kind.
6. If you comply with all requests or have negotiated with the FTC for an agreement, request that they send you a letter documenting your voluntary compliance so that if any other entity investigates or raises a question, you have evidence of compliance.
7. Consult counsel when in doubt, particularly if you wish to maintain some aspect of your current language or sales.

### **Options for Complying with FTC Warning Letters**

This becomes a judgment call depending on your content, your business model, your risk tolerance, and your knowledge of applicable laws (or willingness to obtain legal counsel).

**The Safest Legal Course** is to simply remove the cited passages and review your site for similar material, including metatags.

**Other options:**

- **Remove association to sale of products** - Discuss COVID-19 or anti-viral claims and treatment approaches using dietary ingredients or herbs to mitigate, prevent or cure disease ***without any association to the sale of products or links to online stores*** related to such discussion. Discussion of dietary supplements that you do not offer for sale does not violate dietary supplement rules, but FTC could still raise an issue if they believe it does not have a scientific basis and conflicts with public health policy considerations . **IMPORTANT NOTE FOR OREGON NDs BELOW.**
- **Remove association to COVID-19 and/or anti-viral claims** - if you choose to maintain dietary ingredient sales.
- **Avoid language that is overly exuberant or that implies a guarantee** that is not clinically supportable. Language that an ingredient “may” help, a practice has “had some success,” and other conditional statements are more defensible than statements that a product is “known to” or definitely “increases/enhances x, y z.”
- **Add appropriate disclaimers prominently** on all pages that contain discussion about COVID and/or dietary supplements. See Appendix A.

**Note for Oregon NDs:** While FTC can require that claims must include scientific evidence, the Oregon Department of Justice has adopted a temporary rule to protect consumers from unsubstantiated claims that a good is effective against COVID-19. Effective April 17, 2020, OAR 137-020-0260 makes it unfair or deceptive for sellers or advertisers to represent that a good (which includes dietary supplement) prevents, treats, diagnoses, mitigates or cures coronavirus, COVID-19, or a related condition, without first having competent and reliable scientific evidence (also known as “substantiation”) upon which to base a reasonable belief in the truth of the representation. Note that what constitutes “substantiation” is itself somewhat subjective, but care should especially be taken when connecting claims to COVID-19.

Because research directly related to COVID-19 is extremely limited, NDs in Oregon should recognize that making claims of prevention, treatment, diagnoses, mitigation, or cure for coronavirus, COVID-19, or a related condition could expose them to higher risk of regulatory action in the current environment, and should consider only addressing the management of symptoms (respiratory illness, fever, headaches, digestive issues) to be based upon patient evaluation when providing general treatment recommendations.

Under the temporary rule, making such allegedly unsubstantiated claims is considered a violation of the Unfair Trade Practices Act and the Oregon Department of Justice has issued numerous Civil Investigative Demands to clinics, including to those who received FTC Warning Letters.