U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

January 11, 2018

Richie Ogulnick
2405 NW 31st Terrace
Gainesville, FL 32605-2730

RE: 542770

Dear Mr. Ogulnick:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address, www.taperaid.com, in December 2017 and has determined that you take orders for the products "TaperAid" and "TaperAid Complete." FDA also reviewed your social media website at www.facebook.com/TaperAid. The claims on your websites establish that these products are drugs 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 they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission has reviewed your marketing claims for your "TaperAid" products for potential violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Examples of some of the claims observed on your websites that provide evidence your products are intended for use as drugs include the following:

TaperAid

- "TaperAid helps lower tolerance to opioids, including oxycontin, morphine, oxycodone, opium, Vicodin, demerol, hydrocodone, methadone, suboxone, heroin, and tramadol."
- "TaperAid helps relieve the symptoms of withdrawal."
- "If you choose to detox from opioids completely, use TaperAid to taper down before detoxing."
- "People using short acting opioids (which includes many pain management medications and heroin) will notice a significant lowering of tolerance to their opiate of choice."
- "CAUTION: Use of TaperAid may increase sensitivity to opioids. You may need to lower your usual intake of opioids to account for reduced tolerance."

TaperAid Complete

- "TaperAid Complete helps relieve the symptoms of withdrawal."
- "TaperAid Complete helps detox from opioids, including oxycontin, morphine, oxycodone, opium, vicodin, demerol, hydrocodone, methadone, Suboxone, Heroin, and Tramadol."
- "Continued use of TaperAid Complete will mitigate the symptoms of PAWS (post-acute withdrawal symptoms) such as insomnia, anxiety"

Additional claims observed on your website's FAQ page, www.taperaid.com/faq, that provide evidence that your products are intended for use as drugs include the following:

- "What is the report on heroin? People have reported a significant decrease in tolerance to heroin as well as the ability to jump off with TaperAid Complete."
- "What is the report on painkillers? People using short acting opioids such as hydrocodone, percoset, oxycontin, morphine, etc. have reported a significant decrease in intake as well as the ability to jump off with TaperAid Complete."

Finally, claims made on your Facebook page, www.facebook.com/TaperAid, which links to your website www.taperaid.com where your products can be purchased directly, provide further evidence that your products are intended for use as drugs:

On your Facebook Timeline posts:

- June 12, 2017: "Our first remedy, TaperAid, is for opiate tapering … the remedy reduces withdrawal symptoms during the detox period. TaperAid Complete also mitigates post acute withdrawal symptoms."
- June 7, 2017: "Ryan tapered from 3 grams of heroine [sic] per day to one gram with no discomfort."
- May 7, 2017: "We've created a new formulation that helps with the final stages of opioid detox by relieving the symptoms of withdrawal and PAWs, to be taken after the final opioid intake."
- May 6, 2017: "I have been taking TaperAid for three weeks now and I have cut down the heroin intake by half again."
- May 4, 2017: "My recent habit was … 10mg Hydrocodone approximately 5-10 times daily; but definitely enough to feel withdrawal symptoms if I missed a dose … Two weeks ago, I started taking TaperAid and was able to cut my dose nearly in half within the first week."
- March 21, 2017: "I started using heroin in 2001 … I have tried everything from Methadone, Sebutex, Suboxone and even Ibogain. Nothing had worked for me … So far my experience with TaperAid has been easy. I take what I'm supposed to and I don't get sick as fast as I would without it."
- February 27, 2017: "I only took 20 grams (of TaperAid) over two days and now I can't even take 30 mg of oxycodone. I feel like I took 120 mg … This stuff seems to help me use so much less… Five days later … I'm barely taking any oxy at all now."
- February 11, 2017: "(took 40 mg of Hydrocodone per day for almost four years): 'Three days into using TaperAid … I was late two hours taking a hydro dose and I didn't even

feel any withdrawal. This NEVER happened prior to taking the formula … I am now 50% lower then my abuse dosage"

- February 1, 2017: "TaperAid is a safe and potent herbal dietary supplement that can … reduce cravings for opiates."

Your products "TaperAid" and "TaperAid Complete" are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the 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 CFR 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 products "TaperAid" and "TaperAid Complete" are 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 products safely for their intended purposes. Accordingly, "TaperAid" and "TaperAid Complete" fail to bear adequate directions for their intended uses and, therefore, the products are 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)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Unsubstantiated Advertising

In addition, the Federal Trade Commission has reviewed marketing claims related to opiate withdrawal and/or opiate addiction for your "TaperAid" products. The FTC Act requires that health-related claims, such as claims that a product will treat or cure a disease or other health condition, must be supported by competent and reliable scientific evidence at the time the claims are made. In other words, it is against the law to make health claims, whether directly or indirectly, through advertising, the use of a product name, website name, or any other means, without adequate scientific support, or to exaggerate the benefits of products or services you are promoting. **Violations of the FTC Act may result in legal action in the form of a Federal District Court Injunction or an Administrative Order and may require that you pay money back to consumers.**

Given the claims you are making, you should be aware of two FTC law enforcement actions challenging unsupported claims for the treatment of opiate addiction and/or opiate withdrawal symptoms: *FTC v. Sunrise Nutraceuticals, LLC*, which involved the product Elimidrol, and *FTC v. Catlin Enterprises, Inc.*, which involved the products Withdrawal Ease and Recovery Ease. The complaints and orders in those cases can be found at https://www.ftc.gov/enforcement/cases-proceedings/152-3208-x160006/sunrise-nutraceuticals-llc and https://www.ftc.gov/enforcement/cases-proceedings/1623204/catlin-enterprises-inc. The orders entered in both cases imposed monetary judgments and required the defendants to stop making deceptive claims.

The FTC strongly urges you to review all health-related claims that you and any of your affiliates are making in any medium. Competent and reliable scientific evidence for a product claiming to treat opiate withdrawal symptoms or opiate addiction consists of randomized, controlled, human clinical testing of that product. If any of your claims are not supported by competent and reliable scientific evidence, you should delete or revise them immediately.

With regard to the advertising claims discussed above, please notify Edward Glennon of the FTC via electronic mail at eglennon@ftc.gov, within fifteen working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. With regard to the FDA-related violations described in this letter, please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete corrective action within fifteen working days, please explain the reason for the delay and the date by which you will make the correction. If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. You may respond in writing to Compliance Officer Shawn Goldman at U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

If you have any questions concerning this letter, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,

William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission